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01-001 DEPARTMENT OF AGRICULTURE, FOOD AND RURAL RESOURCES

Chapter 329: RULE GOVERNING MAINE MILK AND MILK PRODUCTS

SUMMARY: This Rule outlines the procedures and standards governing the inspection and examination, licensing, permitting, testing, labeling and sanitation of milk and milk product production and distribution.

STATUTORY AUTHORITY: 7 M.R.S.A. §2910

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(APA Office Note: Please contact the Department of Agriculture, Food and Rural Resources, 28 State House Station, Augusta, ME 04333, phone 207/287-7610, for copies of the following attachments.)

ATTACHMENTS

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DAIRY FARM INSPECTION REPORT
MANUFACTURING PLANT INSPECTION REPORT
MILK PLANT EQUIPMENT TESTS REPORT
BULK MILK PICKUP TANKER, HAULER REPORT AND SAMPLER EVALUATION FORM

SECTION I - GENERAL

A. DEFINITIONS

1. ACIDIFIED MILK -

(a) “Acidified milk” is the food produced by souring one or more of the optional dairy ingredients specified in paragraph (c) of this Section with one or more of the acidifying ingredients specified in paragraph (d) of this Section, with or without the addition of characterizing microbial organisms. One or more of the other optional ingredients specified in paragraph (b) and (e) of this Section may also be added. When one or more of the ingredients specified in paragraph (e)(i) of this Section are used, they shall be included in the souring process. All ingredients used are safe and suitable. Acidified milk contains not less than 3.25 percent milkfat and not less than 8.25 percent milk solids not fat and has a titratable acidity of not less than 0.5 percent, expressed as lactic acid. The food may be homogenized and may be pasteurized or ultra-pasteurized prior to the addition of the microbial culture and, when applicable, the addition of flakes or granules of butterfat or milkfat.

(b) Vitamin addition (optional)

(i) If added, vitamin A shall be present in such quantity that each 946 milliliters (1-quart) of the food contains not less than 2,000 International Units thereof, within limits of good manufacturing practice.

(ii) If added, vitamin D shall be present in such quantity that each 946 milliliters (1-quart) of the food contains 400 International Units thereof, within limits of good manufacturing practice.

(c) Optional dairy ingredients. Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.

(d) Optional acidifying ingredients. Acetic acid, adipic acid, citric acid, fumaric acid, glucono-delta-lactone, hydrochloric acid, lactic acid, malic acid, phosphoric acid, succinic acid, and tartaric acid.

(e) Other optional ingredients.

(i) Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food: provided, that the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present, shall not be decreased as a result of adding such ingredients.

(ii) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or syrup form); brown sugar; refiner's syrup; molasses (other than blackstrap); high fructose corn syrup; fructose; fructose syrup; maltose; maltose syrup, dried maltose syrup; malt extract; dried malt extract; malt syrup, dried malt syrup; honey; maple sugar; or any other sweeteners listed in 21 CFR Part 168, except table syrup.

(iii) Flavoring ingredients.

(iv) Color additives that do not impart a color simulating that of milkfat or butterfat.

(v) Stabilizers.

(vi) Butterfat or milkfat, which may or may not contain color additives, in the form of flakes or granules.

(vii) Aroma- and flavor-producing microbial culture.

(viii) Salt.

(ix) Citric acid, in a maximum amount of 0.15 percent by weight of the dairy ingredients used, or an equivalent amount of sodium citrate, as a flavor precursor.

2. ACIDIFIED SOUR CREAM -

(a) "Acidified sour cream" is the result of the souring of pasteurized cream with safe and suitable acidifiers, with or without addition of lactic acid producing bacteria. Acidified sour cream contains not less than 18 percent milkfat; except that when the food is characterized by the addition of nutritive sweeteners or bulky flavoring ingredients, the weight of the milkfat is not less than 18 percent of the remainder obtained by subtracting the weight of such optional ingredients from the weight of the food; but in no case does the food contain less than 14.4 percent milkfat. Acidified sour cream has a titratable acidity of not less than 0.5 percent, calculated as lactic acid.

(b) Optional ingredients.

(i) Safe and suitable ingredients that improve texture, prevent syneresis, or extend the shelf life of the product.

(ii) Rennet.

(iii) Safe and suitable nutritive sweeteners.

(iv) Salt.

(v) Flavoring ingredients, with or without safe and suitable coloring as follows:

(a) Fruit and fruit juice, including concentrated fruit and fruit juice.

(b) Safe and suitable natural and artificial food flavoring.

3. ACIDIFIED SOUR HALF-AND-HALF -

(a) "Acidified sour half-and half" is the result of the souring of pasteurized half-and-half with safe and suitable acidifiers, and with or without addition of lactic acid producing bacteria. Acidified sour half-and-half contains not less than 10.5 percent but less than 18 percent milkfat; except that when the food is characterized by the addition of nutritive sweeteners or bulky flavoring ingredients, the weight of the milkfat is not less than 10.5 percent of the remainder obtained by subtracting the weight of such optional ingredients from the weight of the food; but in no case does the food contain less than 8.4 percent milkfat. Acidified sour half-and-half has a titratable acidity of not less than 0.5 percent, calculated as lactic acid.

(b) Optional ingredients.

(i) Safe and suitable ingredients to improve texture, prevent syneresis, or extend the shelf life of the product.

(ii) Rennet.

(iii) Safe and suitable nutritive sweeteners.

(iv) Salt.

(v) Flavoring ingredients, with or without safe and suitable coloring, as follows:

(a) Fruit and fruit juice, including concentrated fruit and fruit juice.

(b) Safe and suitable natural and artificial food flavoring.

4. ADULTERATED MILK AND MILK PRODUCTS -

Any milk or milk product shall be deemed to be adulterated:

(a)

(i) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or

(ii)

(a) If it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug) which is unsafe within the meaning of Section 406 of the Federal Food, Drug and Cosmetic Act (hereinafter referred to as FD&C), or

(b) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of Section 408(a) of the FD&C; or

(c) if it is, or it bears or contains, any food additive which is unsafe within the meaning of Section 409 of the FD&C: provided, that where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under Section 408 of the FD&C and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, milling, the residue of such pesticide chemical remaining in or on such processed food shall, not withstanding the provisions of Section 406 and 409 of the FD&C, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity; or

(d) if it is, or it bears or contains, a new animal drug (or conversion product thereof) which is unsafe within the meaning of Section 512 of the FD&C; or

(iii) if it consists in whole or in part of any filthy, putrid or decomposed substance, or if it is otherwise unfit for food; or

(iv) if it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or

(v) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or

(vi) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(vii) if it has been intentionally subjected to radiation, unless the use of radiation was in conformity with a regulation or exemption in effect pursuant to Section 409 of the FD&C.

(b)

(i) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (ii) if any substance has been substituted wholly or in part therefor; or (iii) if damage or inferiority has been concealed in any manner; or (iv) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) If it is, or it bears or contains, a color additive which is unsafe within the meaning of Section 706(a) of the FD&C.

(d) If it is confectionery, and - (i) has partially or completely imbedded therein any non-nutritive object: provided, that this clause shall not apply in the case of any non-nutritive object if such object is of practical functional value to the confectionery product and would not render the product injurious or hazardous to health; (ii) bears or contains any alcohol other than alcohol not in excess of one-half of 1 percent by volume derived solely from the use of flavoring extracts; or (iii) bears or contains any non-nutritive substance: provided, that this clause shall not apply to a safe non-nutritive substance which is in or on confectionery by reason of its use for some practical functional purpose in the manufacture, packaging or storage of such confectionery if the use of the substance does not promote deception of the consumer or otherwise result in adulteration or misbranding in violation of any provision of this rule: and provided further that the Commissioner may, for the purpose of avoiding or resolving uncertainty as to the application of this clause, issue regulations allowing or prohibiting the use of particular non-nutritive substances.

(e) If it is oleomargarine or margarine or butter and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or such oleomargarine or margarine or butter is otherwise unfit for food.

5. AND/OR - Where the term “and/or” is used, “and” shall apply where appropriate; otherwise “or” shall apply.

6. ASEPTIC PROCESSING - "Aseptic processing", when used to describe a milk product, means that the product has been subjected to sufficient heat processing, and packaged in a hermetically sealed container, to conform to the applicable requirements of Title 21 CFR 113 and the provisions of Section V and maintain the commercial sterility of the product under normal non-refrigerated conditions.

7. ASEPTICALLY PROCESSED MILK AND MILK PRODUCTS- "Aseptically processed milk and milk products" are products that have been subjected to sufficient heat processing and packaged in a hermetically sealed ~~in a~~ container, to conform to the applicable requirements of ~~and so thermally processed in conformance with~~ Title 21 CFR 113 and the provisions of Section V ~~this rule so as~~ and to maintain ~~render the~~ the commercial sterility of the product ~~free of microorganisms capable of reproducing in the product~~ under normal non-refrigerated conditions. ~~of storage and distribution. The product shall be free of viable microorganisms (including spores) of public health significance.~~

8. AUTOMATIC MILKING INSTALLATION (AMI) – The term automatic milking installation covers the entire installation of one or more automatic milking units, including the hardware and software utilized in the operation of individual automatic milking units, the animal selection system, the automatic milking machine, the milk cooling system, the system for cleaning and sanitizing the automatic milking unit, the teat cleaning system, and the alarm systems associated with the process of milking, cooling, cleaning and sanitation.

~~8~~9 BULK MILK HAULER/SAMPLER – "A bulk milk hauler/sampler" is any person who collects official samples and/or transports raw milk from a farm and/or raw milk products to or from a farm, milk plant, receiving station or transfer station and has in their possession a permit from any state to sample such products.

~~9~~10. BULK MILK PICKUP TANKER – "A bulk milk pickup tanker" is a vehicle, including the truck, tank and those appurtenances necessary for its use, used by the bulk milk hauler/sampler or milk tank truck driver to transport bulk raw milk for pasteurization or processing from a dairy farm to a milk plant, receiving station or transfer station.

~~10~~11. BUTTER – "Butter" means the food product which is made exclusively from milk or cream or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80% by weight of milk fat.

~~11~~12. BUTTERMILK - "Buttermilk" is a fluid product resulting from the manufacture of butter from milk or cream. It contains not less than 8 1/4 percent of milk solids not fat.

~~12~~13. CHEESE - "Cheese" is the consolidated curd of milk used as an article of food.

~~13~~14. COMMISSIONER – "Commissioner" means the Commissioner of the Maine Department of Agriculture, Food and Rural Resources or ~~his/her~~ their duly authorized agent.

~~14~~15. CONCENTRATED MILK – "Concentrated milk" is a fluid product, unsterilized and unsweetened, resulting from the removal of a considerable portion of the

water from the milk, which, when combined with potable water in accordance with instructions printed on the container, results in a product conforming with the milkfat and milk solids not fat levels of milk as defined in this section.

16. COOLING POND – A cooling pond is a man-made structure designed for the specific purpose of cooling cows.

~~15~~17. COTTAGE CHEESE -

(a) "Cottage cheese" is the soft uncured cheese prepared by mixing cottage cheese dry curd with a creaming mixture as provided in paragraph (b) of this Section. The milkfat content is not less than 4 percent by weight of the finished food, within limits of good manufacturing practice. The finished food contains not more than 80 percent of moisture.

(b) The creaming mixture is prepared from safe and suitable ingredients including, but not limited to, milk or substances derived from milk. Any ingredients used that are not derived from milk shall serve a useful function other than building the total solids content of the finished food, and shall be used in a quantity not greater than is reasonably required to accomplish their intended effect. The creaming mixture may be pasteurized; however, heat labile ingredients, such as bacterial starters, may be added following pasteurization.

(c) The name of the food consists of the following two phrases which shall appear together:

(i) The words "cottage cheese" which shall appear in type of the same size and style.

(ii) The statement "not less than ... percent milkfat" or "... percent milkfat minimum", the blank being filled in with the whole number that is closest to, but does not exceed, the actual fat content of the product. This statement of fat content shall appear in letters not less than one-half of the height of letters in the phrase specified in paragraph (c)(i) of this Section, but in no case less than one-eighth of an inch in height.

(d) When the optional process described in Title 21 CFR 133 is used to make the cottage cheese dry curd, the label shall bear the statement "directly set" or "Curd set by direct acidification". Wherever the name of the food appears on the label so conspicuously as to be seen under customary conditions of purchase, the statement specified in this paragraph, showing the optional process used shall immediately and conspicuously precede or follow such name without intervening written, printed, or graphic matter.

(e) The common or usual name of each of the ingredients used in the food shall be declared on the label as required by the applicable sections. Except that:

(i) Concentrated milk, dried milk, and reconstituted milk prepared by addition of water to concentrated milk or dried milk may be declared as “milk”.

(ii) Concentrated skim milk, nonfat dry milk, and reconstituted skim milk prepared by addition of water to concentrated skim milk or nonfat dry milk may be declared as “skim milk”.

(iii) Bacterial cultures may be declared by the word “cultured” followed by the name of the substrate, e.g., “made from cultured skim milk”.

(iv) Milk-clotting enzymes may be declared by the word “enzymes”.

~~16~~18. CREAM – “Cream” is the liquid milk product high in fat separated from milk, which may have been adjusted by adding thereto: Milk, concentrated milk, dry whole milk, skim milk, concentrated skim milk, or nonfat dry milk. Cream contains not less than 18 percent milkfat.

~~17~~19. CULTURED MILK -

(a) “Cultured milk” is the food produced by culturing one or more of the optional dairy ingredients specified in paragraph (c) of this Section with characterizing microbial organisms. One or more of the other optional ingredients specified in paragraphs (b) and (d) of this Section may also be added. When one or more of the ingredients specified in paragraph (d)(i) of this Section are used, they shall be included in the culturing process. All ingredients used are safe and suitable. Cultured milk contains not less than 3.25 percent milkfat and not less than 8.25 percent milk solids not fat and has a titratable acidity of not less than 0.5 percent, expressed as lactic acid. The food may be homogenized and may be pasteurized or ultra-pasteurized prior to the addition to the microbial culture, and when applicable, the addition of flakes or granules of butterfat or milkfat.

(b) Vitamin addition (optional).

(i) If added, vitamin A shall be present in such quantity that each 946 milliliters (1-quart) of the food contains not less than 2,000 International Units thereof within limits of good manufacturing practice.

(ii) If added, vitamin D shall be present in such quantity that each 946 milliliters (1-quart) of the food contains 400 International Units thereof, within limits of good manufacturing practice.

(c) Optional dairy ingredients. Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.

(d) Other optional ingredients.

(i) Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food: provided, that the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present, shall not be decreased as a result of adding such ingredients.

(ii) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or syrup form); brown sugar; refiner's syrup; molasses (other than blackstrap); high fructose corn syrup; fructose; fructose syrup; maltose; maltose syrup, dried maltose syrup; malt extract, dried malt extract; malt syrup, dried malt syrup; honey; maple sugar; or any other sweetener listed in 21 CFR Part 168, except table syrup.

(iii) Flavoring ingredients.

(iv) Color additives that do not impart a color simulating that of milkfat or butterfat.

(v) Stabilizers.

(vi) Butterfat or milkfat, which may or may not contain color additives, in the form of flakes or granules.

(vii) Aroma- and flavor-producing microbial culture.

(viii) Salt.

(ix) Citric acid, in a maximum amount of 0.15 percent by weight of the milk used, or an equivalent amount of sodium citrate, as a flavor precursor.

~~18~~20. DAIRY OR DAIRY FARM – "Dairy or dairy farm" means any place or premises where one or more cows, goats, ~~or~~ sheep, water buffalo, or other hooved mammal are kept, and from which a part or all of the milk or milk product(s) are sold or offered for sale.

~~19~~21. DAIRY PLANT SAMPLER - A "dairy plant sampler" is an individual responsible for the collection of official samples for regulatory purposes. These persons are employees of the Department or an official designee of the Department and are evaluated every two years by the State Sample Surveillance Officer.

~~20~~22. DEPARTMENT - "Department" means the Maine Department of Agriculture, Food and Rural Resources.

~~21~~23. DRUG - The term "drug" means (a) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official National Formulary or any supplement to any of them; and (b) articles

intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; and (c) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (d) articles intended for use as a component of any articles specified in clause (a), (b) or (c), but does not include devices or their components, parts or accessories.

~~22~~24. DRY CURD COTTAGE CHEESE -

(a) "Dry curd cottage cheese" is the soft uncured cheese prepared by the procedure set forth in paragraph (b) of this Section. The finished food contains less than 0.5 percent milkfat. It contains not more than 80 percent of moisture.

(b)

(i) One or more of the dairy ingredients specified in paragraph (b)(ii) of this section is pasteurized; calcium chloride may be added in a quantity of not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the mix; thereafter one of the following methods is employed:

(a) Harmless lactic-acid-producing bacteria, with or without rennet and/or other safe and suitable milk clotting enzyme that produces equivalent curd formation, are added and it is held until it becomes coagulated. The coagulated mass may be cut; it may be warmed; it may be stirred; it is then drained. The curd may be washed with water and further drained; it may be pressed, chilled, worked, seasoned with salt; or

(b) Food grade phosphoric acid, lactic acid, citric acid, or hydrochloric acid, with or without rennet and/or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, is added in such amount as to reach a pH of between 4.5 and 4.7; coagulation to a firm curd is achieved while heating to a maximum of 48.9°C (120°F) without agitation during a continuous process. The coagulated mass may be cut; it may be warmed; it may be stirred; it is then drained. The curd is washed with water, stirred, and further drained. It may be pressed, chilled, worked~~,~~ and seasoned with salt.

(c) Food grade acids as provided in paragraph (b)(i)(b) of this Section, D-Glucono- delta-lactone with or without rennet, and/or other safe and suitable milk clotting enzyme that produces equivalent curd formation, are added in such amounts as to reach a final pH value ~~is~~ in the range of 4.5-4.8, and it is held until it becomes coagulated. The coagulated mass may be cut; it may be warmed; it may be stirred; it is then drained. The curd is

then washed with water, and further drained. It may be pressed, chilled, worked, and seasoned with salt.

(ii) The dairy ingredients referred to in paragraph (b)(i) of this Section are sweet skim milk, concentrated skim milk, and nonfat dry milk. If concentrated skim milk or nonfat dry milk is used, water may be added in a quantity not in excess of that removed when the skim milk was concentrated or dried.

(iii) For the purposes of this Section the term "skim milk" means the milk of cows from which the milk fat has been separated, and "concentrated skim milk" means skim milk from which a portion of the water has been removed by evaporation.

(c) The name of the food consists of the following two phrases which shall appear together:

(i) The words "cottage cheese dry curd" or alternatively "dry curd cottage cheese" which shall all appear in type of the same size and style.

(ii) The words "less than 1/2% milkfat" which shall all appear in letters not less than one-half of the height of the letters in the phrase specified in paragraph (c)(i) of this Section, but in no case less than one-eight of an inch in height.

(d) When either of the optional processes described in paragraph (b)(i) (b) or (c) of this Section is used bear the statement "Directly set" or "Curd set by direct acidification". Wherever the name of the food appears on the label so conspicuously as to be seen under customary conditions of purchase, the statement specified in this paragraph, showing the optional process used, shall immediately and conspicuously precede or follow such name without intervening written, printed, or graphic matter.

(e) The common or usual name of each of the ingredients used in the food shall be declared on the label as required in Section XIV of this rule, except that:

(i) Concentrated skim milk, nonfat dry milk, and reconstituted skim milk prepared by addition of water to concentrated skim milk or nonfat dry milk may be declared as "skim milk".

(ii) Bacterial cultures may be declared by the word "cultured" followed by the name of the substrate, e.g., "made from cultured skim milk".

(iii) Milk-clotting enzymes may be declared by the word "enzymes".

~~23~~25. EGGNOG -

(a) "Eggnog" is the food containing one or more of the optional dairy ingredients specified in paragraph (b), one or more of the optional egg yolk-containing ingredients specified in paragraph (c) of this Section, and one or more of the optional nutritive carbohydrate sweeteners specified in paragraph (d) of this Section. One or more of the optional ingredients specified in paragraph (e) of this Section may also be added. All ingredients used are safe and suitable. Eggnog contains not less than 6 percent milkfat and not less than 8.25 percent milk solids not fat. The egg yolk solids content is not less than 1 percent by weight of the finished food. The food shall be pasteurized or ultra-pasteurized and may be homogenized. Flavoring ingredients and color additives may be added after the food is pasteurized or ultra-pasteurized.

(b) Optional dairy ingredients. Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.

(c) Egg Yolk-containing ingredients. Liquid egg yolk, frozen egg yolk, dried egg yolk, liquid whole eggs, frozen whole eggs, dried whole eggs, or any one or more of the foregoing ingredients with liquid egg whites or frozen egg whites.

(d) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or syrup form); brown sugar; refiner's syrup; molasses (other than blackstrap); high fructose corn syrup; fructose, fructose syrup; maltose; maltose syrup, dried maltose syrup; malt extract, dried malt extract; malt syrup, dried malt syrup; honey; maple sugar; or any of the sweeteners listed in 21 CFR Part 168, except table syrup.

(e) Other optional ingredients.

(i) Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food: provided, that the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present, shall not be decreased as a result of adding such ingredients.

(ii) Salt.

(iii) Flavoring ingredients.

(iv) Color additives that do not impart a color simulating that of egg yolk, milkfat or butterfat.

(v) Stabilizers.

~~24~~26. FALSE POSITIVE – In reference to antibiotic screening of bulk tanker milk and bulk tank milk, "false positive" means that, on subsequent testing by high pressure chromatograph (HPLC), antibiotic residue was not found to be present.

~~25~~27. FALSE VIOLATIVE – In reference to antibiotic screening of bulk tanker milk or bulk tank milk, "false violative" means that on subsequent testing by high pressure liquid chromatograph, antibiotic residue was found to be present at below the FDA-established safe or tolerance level.

~~26~~28. FOOD ALLERGENS: Are proteins in foods that are capable of inducing an allergic reaction or response in some individuals. There is scientific consensus that the following foods account for more than 90 % of all food allergies: peanuts, soybeans, milk, eggs, fish, crustacea, tree nuts, and wheat.

~~27. FROZEN DAIRY DESSERT - "Frozen Dairy Dessert" means ice cream and frozen custard, goat milk ice cream, sherbet and frozen yogurt.~~

~~28. FROZEN DAIRY DESSERT MIX - "Frozen dairy dessert mix" means any unfrozen mixture to be used in the manufacture of frozen dairy dessert for sale or resale and shall contain in whole or in part the ingredients enumerated under the definition of frozen dairy dessert.~~

29. FROZEN MILK - CONCENTRATE – "Frozen milk concentrate" is a frozen milk product with a composition of milkfat and milk solids not fat in such proportions that when a given volume of concentrate is mixed with a given volume of water the reconstituted product conforms to the milkfat and milk solids not fat requirements of whole milk. In the manufacturing process, water may be used to adjust the primary concentrate to the final desired concentration. The adjusted primary concentrate is pasteurized, packaged, and immediately frozen. This product is stored, transported and sold in the frozen state.

30. FROZEN YOGURT

(a) "Frozen yogurt" is the food which is prepared by freezing while stirring a pasteurized mix consisting of the ingredients identified for ice cream. Safe and suitable sweetening agents may be used. Such ingredients are cultured after pasteurization by one or more strains of lactobacillus bulgaricus and streptococcus thermophilus, provided, however, fruit, nuts, or other flavoring materials may be added before or after the mix is pasteurized and cultured. The standard plate count requirement for frozen desserts shall apply to the mix prior to culturing. Frozen yogurt, exclusive of any flavoring contains not less than 3.25 percent milkfat, not less than 8.25 percent milk solids not fat and has a titratable acidity of not less than 0.3 percent expressed as lactic acid. Where the titratable acidity of the frozen yogurt is less than 0.3 percent, the manufacturer may establish compliance with this section by disclosing to the ~~regulatory authority~~ Department its quality control records that demonstrate as a result of bacterial culture fermentation, at least a 0.15 percent increase in titratable acidity calculated as lactic acid, above the apparent titratable acidity of the uncultured dairy ingredients in the frozen yogurt mix. The direct

addition of food grade acids or other acidogens for the purpose of raising the titratable acidity of the frozen yogurt mix to comply with the prescribed minimum is not permitted; and no chemical preservative treatment or other preservation process, other than refrigeration, may be utilized that results in reduction of the live culture. Sweetener(s), flavoring(s) and/or other characterizing food ingredients may be added to the mix before or after pasteurization or ultra pasteurization is done in accordance with good manufacturing practice. The finished yogurt shall weigh not less than 4 pounds per gallon. Any dairy ingredients added after pasteurization or ultra pasteurization shall have been pasteurized.

(b) The name of the food is "frozen yogurt". In addition to all other required information, the label shall contain a complete list of ingredients, in accordance with the provisions of 21 CFR 101.4, and comply with the provisions of subdivisions (h) and (i) of 21 CFR 101.22. On the label of frozen yogurt the strains of bacteria may be collectively referred to as yogurt culture.

31. GOAT MILK – "Goat milk" is the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one or more healthy goats. Goat milk sold in retail packages shall contain not less than 2.5 percent milkfat and not less than 7.5 percent milk solids not fat. Goat milk shall be produced according to the sanitary standards of this rule.

32. GOAT'S MILK ICE CREAM

(a) "Goat's milk ice cream" is the food prepared in the same manner prescribed in 21 CFR 135, and complies with all the provisions of 21 CFR 135, except that the only optional dairy ingredients that may be used are those in paragraph (b) of this Section; caseinates and hydrolyzed milk proteins may not be used; and paragraph (f)(i) and (g) of Sec. 135.110 shall not apply.

(b) Optional dairy ingredients. The optional dairy ingredients referred to in paragraph (a) of this Section are goat's skim milk, goat's milk, and goat's cream. These optional dairy ingredients may be used in liquid, concentrated, and/or dry form.

33. GRADE A DRY MILK AND WHEY PRODUCTS - "Grade A dry milk and whey products" are products which have been produced for use in Grade A pasteurized or aseptically processed milk products and which have been manufactured under the provisions of the Grade A Condensed and Dry Milk Products and Condensed and Dry Whey-Supplement I to the Grade A Pasteurized Milk Ordinance, 1995 Recommendations.

34. GRAS – "GRAS" means generally recognized as safe as defined by 21 CFR Part 184.

35. HACCP – “HACCP” means Hazard Analysis and Critical Control Point, it is a food safety control system based on technical and scientific principles that assure safe food.

36. HALF-AND-HALF-

(a) “Half-and-half” is the food consisting of a mixture of milk and cream which contains not less than 10.5 percent but less than 18 percent milkfat. It may be homogenized.

(b) Optional ingredients. The following safe and suitable optional ingredients may be used.

(i) Emulsifiers.

(ii) Stabilizers.

(iii) Nutritive sweeteners.

(iv) Characterizing flavoring ingredients (with or without safe and suitable coloring) as follows:

(a) Fruit and fruit juice (including concentrated fruit and fruit juice)

(b) Natural and artificial food flavoring.

37. HEAVY CREAM OR HEAVY WHIPPING CREAM-

(a) “Heavy cream” is cream which contains not less than 36 percent milkfat. It may be homogenized.

(b) Optional ingredients. The following safe and suitable optional ingredients may be used:

(i) Emulsifiers.

(ii) Stabilizers.

(iii) Nutritive sweeteners.

(iv) Characterizing flavoring ingredients (with or without coloring) as follows:

(a) Fruit and fruit juice (including concentrated fruit and fruit juice).

(b) Natural and artificial food flavorings.

38. HERMETICALLY SEALED CONTAINER - A “hermetically sealed container” is a container that is designed and intended to be secure against the entry of microorganisms and thereby maintain the commercial sterility of its contents after processing.

39. HOMOGENIZED - The term “homogenized” means that milk or a milk product has been treated to insure breakup of the fat globules to such an extent that, after 48 hours of quiescent storage at 4.4°C (40°F), no visible cream separation occurs on the milk; and the fat percentage of the top 100 milliliters of milk in a quart, or of proportionate volumes in containers of other sizes, does not differ by more than 10 percent from the fat percentage of the remaining milk as determined after thorough mixing.

40. HOOVED MAMMALS MILK – Hooved mammals milk is the normal lacteal secretion, practically free of colostrums, obtained by the complete milking of one (1) or more healthy hooved mammals. This product shall be produced according to the sanitary standards of this Rule.

~~40~~41. ICE CREAM AND FROZEN CUSTARD -

(a)

(i) “Ice cream” is a food produced by freezing, while stirring, a mix consisting of one or more of the optional dairy ingredients specified in paragraph (b) of this Section, and may contain one or more of the optional caseinates specified in paragraph (c) of this Section subject to the conditions hereinafter set forth, one or more of the optional hydrolyzed milk proteins as provided for in paragraph (d) of this Section subject to the conditions hereinafter set forth, and other safe and suitable nonmilk-derived ingredients; and excluding other food fats, except such as are natural components of flavoring ingredients used or are added in incidental amounts to accomplish specific functions. Ice cream is sweetened with safe and suitable sweeteners and may be characterized by the addition of flavoring ingredients. If eggs or egg yolk solids are used as an ingredient, they must be pasteurized or, if not, the mix must be pasteurized after the eggs or egg yolk solids are added.

(ii) Ice cream contains not less than 1.6 pounds of total solids to the gallon, and weighs not less than 4.5 pounds to the gallon. Ice cream contains not less than 10 percent milk fat, nor less than 10 percent nonfat milk solids, except that when it contains milkfat at 1 percent increments above the 10 percent minimum, it may contain the following milkfat-to-nonfat milk solids levels:

Percent milkfat	Minimum percent non-fat milk solids
10	10
11	9
12	8

13 7
14 6

Except that when one or more bulky flavors are used, the weights of milkfat and total milk solids are not less than 10 percent and 20 percent, respectively, of the remainder obtained by subtracting the weight of the bulky flavors from the weight of milkfat or total milk solids less than 8 percent and 16 percent, respectively, of the weight of the finished food. Except in the case of frozen custard, ice cream contains less than 1.4 percent egg yolk solids by weight of the food, exclusive of the weight of any bulky flavoring ingredients used. Frozen custard shall contain 1.4 percent egg yolk solids by weight of the finished food: provided, however, that when bulky flavors are added the egg yolk solids content of frozen custard may be reduced in proportion to the amount of weight of the bulky flavors added, but in no case is the content of egg yolk solids in the finished food less than 1.12 percent. A product containing egg yolk solids in excess of 1.4 percent, the maximum set forth in this paragraph for ice cream, may be marketed if labeled as specified by paragraph (e)(i) of this Section.

(iii) When calculating the minimum amount of milkfat and nonfat milk solids required in the finished food, the solids of chocolate or cocoa shall be considered a bulky flavoring ingredient. In order to make allowance for additional sweetening ingredients needed when certain bulky ingredients are used, the weight of chocolate or cocoa solids, used may be multiplied by 2.5; the weight of fruit or nuts used may be multiplied by 1.4; and the weight of partially or wholly dried fruits or fruit juices may be multiplied by appropriate factors to obtain the original weights before drying and this weight may be multiplied by 1.4.

(b) Optional dairy ingredients. The optional dairy ingredients referred to in paragraph (a) of this Section are: cream, dried cream, plastic cream, (sometimes known as concentrated milk fat), butter, butteroil, milk concentrated milk, evaporated milk, sweetened condensed milk, superheated condensed milk, dried milk, skim milk, concentrated skim milk, evaporated skim milk, condensed skim milk, superheated condensed skim milk, sweetened condensed skim milk, sweetened condensed part skim milk, nonfat dry milk, sweet cream buttermilk, condensed sweet cream buttermilk, dried sweet cream buttermilk, skim milk that has been concentrated and from which part of the lactose has been removed by crystallization, skim milk in concentrated or dried form which has been modified by treating the concentrated skim milk with calcium hydroxide and disodium phosphate, and whey and those modified whey products (e.g., reduced lactose whey, reduced minerals whey, and whey protein concentrated) that have been determined by FDA to be generally recognized as safe (GRAS) for use in this type of food. Water may be added, or water may be evaporated from the mix. The sweet cream buttermilk and the concentrated cream buttermilk or

dried sweet cream buttermilk, when adjusted with water to a total solids content of 8.5 percent, has a titratable acidity of not more than 0.17 percent calculated as lactic acid. The term “milk” as used in this Section means cow’s milk. Any whey and modified whey products used contribute, singly or in combination, not more than 25 percent by weight of the total nonfat milk solids content to be finished food. The modified skim milk, when adjusted with water to a total solids content of 9 percent is substantially free of lactic acid as determined by titration within 0.1N NaOH, and it has a pH value in the range of 8.0 to 8.3.

(c) Optional caseinates. The optional caseinates referred to in paragraph (a) of this Section may be added to ice cream mix containing not less than 20 percent total milk solids are: Casein prepared by precipitation with gums, ammonium caseinate, calcium caseinate, potassium caseinate, and sodium caseinate. Caseinate may be added in liquid or dry form, but must be free of excess alkali.

(d) Optional hydrolyzed milk proteins. One or more of the optional hydrolyzed milk proteins referred to in paragraph (a) of this Section may be added as stabilizers at a level not to exceed 3 percent by weight of ice cream mix containing not less than 20 percent total milk solids provided that any whey and modified whey products used contribute, singly or in combination, not more than 25 percent by weight of the total nonfat milk solids content of the finished food. Further, when hydrolyzed milk proteins are used in the food, the declaration of these ingredients on the food label shall comply with the requirements of Section XIV.

(e) Nomenclature.

(i) The name of the food is "ice cream", except that when the egg yolk solids content of the food is in excess of that specified for ice cream by paragraph (a) of this Section the name of the food is “frozen custard” or “french ice cream” or “french custard ice cream”.

(ii)

(a) If the food contains no artificial flavor, the name on the principal display panel or panels of the label shall be accompanied by the common or usual name of the characterizing flavor, e.g., "vanilla" in letters not less than one-half the height of the letters used in the words "ice cream”.

(b) If the food contains both a natural characterizing flavor and an artificial flavor simulating it, and if the natural flavor predominates, the name on the principal display panel or panels shall be accompanied by the common name of the characterizing flavor, in letters not less than one-half the height of the letters used in the words “ice cream” followed

by the word "flavored", in letters not less than one half the height of the letters in the name of the characterizing flavor, e.g. "vanilla flavored", or "peach flavored", or "vanilla flavored and strawberry flavored".

(c) If the food contains both a natural characterizing flavor and an artificial flavor simulating it, and if the artificial flavor predominates, or if the artificial flavor is used alone, the name on the principal display panel or panels of the label shall be accompanied by the common name of the characterizing flavor in letters not less than one-half the height of the letters used in the words "ice cream", preceded by "artificial" or “artificially flavored", in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g. "artificial vanilla", “artificially flavored strawberry" or "artificially flavored vanilla and artificially flavored strawberry".

(iii)

(a) If the food is subject to the requirements of paragraph (e)ii(b) of this section or if it contains any artificial flavor not simulating the characterizing flavor, the label shall also bear the word "artificial flavor added" or "artificial _____ flavor added", the blank being filled in with the common name of the flavor simulated by the artificial flavor in letters of the same size and prominence as the words that precede and follow it.

(b) Whenever the name of the characterizing flavor appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words prescribed by this paragraph shall immediately and conspicuously precede or follow such name, in a size reasonably related to the prominence of the name of the characterizing flavor and in any event the size of the type is not less than 6-point on packages containing at least 1 pint but less than one-half gallon, not less than 10-point on packages containing at least one-half gallon but less than 1 gallon, and not less than 12-point on packages containing 1 gallon or over: provided, however, that where the characterizing flavor and a trademark or brand are presented together, other written, printed, or graphic matter that is a part of or is associated with the trademark or brand, may intervene if the required words are in such relationship with the trademark or brand as to be clearly related to the characterizing flavor, and provided further, that if the finished product contains more than one flavor of ice cream subject to the requirements of this paragraph, the statements required by this paragraph need

appear only once in each statement of characterizing flavors present in such ice cream, e.g. "Vanilla flavored, chocolate and strawberry flavored, artificial flavors added".

(iv) If the food contains both a natural characterizing flavor and an artificial flavor simulating the characterizing flavor, any reference to the natural characterizing flavor shall, except as otherwise authorized by this paragraph, be accompanied by a reference to the artificial flavor, displayed with subsequently equal prominence, e.g. “strawberry and artificial strawberry flavor".

(v) An artificial flavor simulating the characterizing flavor shall be deemed to predominate:

(a) In the case of vanilla beans or vanilla extracts used in combination with vanillin if the amount of vanillin used is greater than 1 ounce per unit of vanilla constituent as defined in 21 CFR part 169.

(b) In the case of fruit or fruit juice used in combination with artificial fruit flavor, if the quantity of the fruit or fruit juice used is such that, in relation to the weight of the finished ice cream, the weight of the fruit or fruit juice, as the case may be (including water necessary to reconstitute partially or wholly dried fruits or fruit juices to their original moisture content) is less than 2 percent in the case of citrus ice cream, 6 percent in the case of berry or cherry ice cream, and 10 percent in the case of ice cream prepared with other fruits.

(c) In the case of nut meats used in combination with artificial nut flavor, if the quantity of the nut meats is such that, in relation to the finished ice cream the weight of the nut meats is less than 2 percent.

(d) In the case of two or more fruits or fruit juices, or nut meats, or both, used in combination with artificial flavors simulating the natural flavors and dispersed throughout the food, if the quantity of any fruit or fruit juice or nut meat is less than one-half the applicable percentage specified in paragraph (e)(5)(b) or (c) of this Section. For example, if a combination of ice cream contains less than 5 percent of bananas and less than 1 percent of almonds it would be “artificially flavored banana-almond ice cream”. However, if it contains more than 5 percent of bananas and more than 1 percent of almonds it would be banana-almond flavored ice cream”.

(vi) If two or more flavors of ice cream are distinctively combined in one package, e.g., "Neapolitan" ice cream, the applicable provisions of this paragraph shall govern each flavor of ice cream comprising the combination.

(vii) Each of the optional ingredients used shall be declared on the label as required by the applicable section of 21 CFR 101, except that sources of milkfat or milk solids not fat may be declared in descending order of predominance either by the use of the terms "milkfat and nonfat milk" when one or any combination of two or more of the ingredients listed in 21 CFR 101 are used or alternatively as permitted in 21 CFR 101. Pursuant to the FD & C, artificial color need not be declared in ice cream. Voluntary declaration of such color in ice cream is recommended.

~~41~~42. ICE CREAM MIX - "Ice cream mix" is the unfrozen product from which ice cream is manufactured. When applicable, the ingredient and butterfat standards shall be the same for ice cream.

43. INDUSTRY PLANT SAMPLER – A person responsible for the collection of official samples for regulatory purposes at a milk plant, receiving station or transfer station as outlined in Section XIII. of this Rule. This person is an employee of the milk plant, receiving station or transfer station and is evaluated at least once every two (2) year period by a State Sampling Surveillance Officer or a properly delegated Sampling Surveillance Regulatory Official.

~~42~~44. LACTOSE-REDUCED MILK– "Lactose-reduced milk" is the product resulting from the treatment of milk, as defined in this rule, by the addition of safe and suitable enzymes to convert sufficient amounts of the lactose to glucose and/or galactose so that the remaining lactose is less than 30 percent of the lactose in milk.

~~43~~45. LIGHT CREAM -

(a) "Light cream" is cream which contains not less than 18 percent but less than 30 percent milkfat. It may be homogenized.

(b) Optional ingredients. The following safe and suitable optional ingredients may be used:

(i) Stabilizers.

(ii) Emulsifiers.

(iii) Nutritive Sweeteners.

(iv) Characterizing flavoring ingredients (with or without coloring) as follows:

(a) Fruit and fruit juice (including concentrated fruit and fruit juice)

(b) Natural and artificial food flavorings.

~~44~~46. LIGHT MILK –

(a) "Light milk" is milk that has less than or equal to 4 grams of fat per 8 ounce (240 mL) serving and contains not less than 8.25 percent milk solids not fat.

(b) Vitamin addition.

(i) Vitamin A shall be present in such quantity that each 946 milliliters (1 quart) of the food contains not less than 2,000 International Units thereof within limits of good manufacturing practice.

(ii) Addition of vitamin D is optional. If added, vitamin D shall be present in such quantity that each 946 milliliters (1 quart) of the food contains 400 International Units thereof within limits of good manufacturing practice.

~~45~~47. LIGHT WHIPPING CREAM, MEDIUM CREAM OR WHIPPING CREAM -

(a) "Light whipping cream, medium cream or whipping cream" is cream which contains not less than 30 percent but less than 36 percent milkfat. It may be homogenized.

(b) Optional ingredients. The following safe and suitable optional ingredients may be used:

(i) Stabilizers.

(ii) Emulsifiers.

(iii) Nutritive sweeteners.

(iv) Characterizing flavoring ingredients (with or without coloring) as follows:

(a) Fruit and fruit juice (including concentrated fruit and fruit juice).

(b) Natural and artificial food flavorings.

~~46~~48. LOW-SODIUM MILK– "Low-sodium milk" is the product resulting from the treatment process of passing milk through an ion exchange resin process that effectively reduces the sodium content of the product to less than 10 milligrams in 100 milliliters.

~~47~~49. LOWFAT MILK –

(a) "Lowfat milk" is milk that has between 0.5 and 3 grams of fat per 8 ounce (240 mL) serving and contains not less than 8.25 percent milk solids not fat.

(b) Vitamin addition.

(i) Vitamin A shall be present in such quantity that each 946 milliliters (1 quart) of the food contains not less than 2,000 International Units thereof within limits of good manufacturing practice.

(ii) Addition of vitamin D is optional. If added, vitamin D shall be present in such quantity that each 946 milliliters (1 quart) of the food contains 400 International Units thereof within limits of good manufacturing practice.

~~48~~50. LOWFAT YOGURT -

(a) "Low-fat yogurt" is the food produced by culturing one or more of the optional dairy ingredients specified in paragraph (c) of this Section with a characterizing bacterial culture that contains the lactic acid-producing bacteria, Lactobacillus bulgaricus and Streptococcus thermophilus. One or more of the other optional ingredients specified in paragraph (b) and (d) of this Section may also be added. When one or more of the ingredients specified in paragraphs (d)(i) of this Section are used, they shall be included in the culturing process. All ingredients used are safe and suitable. Low-fat yogurt, before the addition of bulky flavors, contains not less than 0.5 percent nor more than 2 percent milkfat and not less than 8.25 percent milk solids not fat, and has a titratable acidity of not less than 0.9 percent, expressed as lactic acid. The food may be homogenized and shall be pasteurized or ultra-pasteurized prior to the addition of the bacterial culture. Flavoring ingredients may be added after pasteurization or ultra-pasteurization. To extend the shelf life of the food, low-fat yogurt may be heat-treated after culturing is completed, to destroy viable microorganisms.

(b) Vitamin addition (optional).

(i) If added, vitamin A shall be present in such quantity that each 946 milliliters (1-quart) of the food contains not less than 2,000 International Units thereof, within limits of current good manufacturing practice.

(ii) if added, vitamin D shall be present in such quantity that each 946 milliliters (1-quart) of the food contains 400 International Units thereof, within limits of current good manufacturing practice.

(c) Optional dairy ingredients. Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.

(d) Other optional ingredients.

(i) Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food: provided, that the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present shall not be decreased as a result of adding such ingredients.

(ii) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or syrup form); brown sugar; refiner's syrup; molasses (other than blackstrap); high fructose corn syrup; fructose; fructose syrup; maltose; maltose syrup, dried maltose syrup; malt extract, dried malt extract; malt syrup, dried malt syrup; honey; maple sugar; or any other sweetener listed in 21 CFR Part 168, except table syrup.

(iii) Flavoring ingredients.

(iv) Color additives.

(v) Stabilizers.

~~49~~51. MILK -

(a) "Milk" is the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows, goats, ~~or~~ sheep, water buffalo or other hooved mammal. Milk from cows that is in final package form for beverage use shall contain not less than 8-1/4 percent milk solids not fat and not less than 3-1/4 percent milkfat. Milk may have been adjusted by separating part of the milkfat therefrom, or by adding thereto cream, concentrated milk, dry whole milk, skim milk, concentrated skim milk, or nonfat dry milk. Milk may be homogenized.

(b) Vitamin addition (optional).

(i) If added, vitamin A shall be present in such quantity that each 946 milliliters (1-quart) of the food contains not less than 2000 International Units thereof within limits of good manufacturing practice.

(ii) If added, vitamin D shall be present in such quantity that each 946 milliliters (1-quart) of the food contains 400 International Units thereof within limits of good manufacturing practice.

(c) Optional Ingredients. The following safe and suitable ingredients may be used.

(i) Carriers for vitamin A and D.

(ii) Characterizing flavoring ingredients (with or without coloring, nutritive sweetener, emulsifiers, and stabilizers) as follows:

(a) Fruit and fruit juice (including concentrated fruit and fruit juice).

(b) Natural and artificial food flavorings.

~~50~~52. MILK DISTRIBUTOR - A “milk distributor” is any person who offers for sale or sells to another any milk or milk products in its final form.

~~51~~53. MILK PLANT – “Milk plant” means any place, premises or establishment where milk or milk products are collected, handled, processed, stored, pasteurized, aseptically processed, bottled or otherwise prepared for distribution and subsequent sale.

~~52~~54. MILK PRODUCER – “Milk producer” means any person who operates a dairy farm and provides, sells or offers milk or milk product(s) for sale.

~~53~~55. MILK PRODUCTS - “Milk products” include cream, light cream, light whipping cream, heavy cream, heavy whipping cream, whipped cream, whipped light cream, sour cream, acidified sour cream, cultured sour cream, milk, butter, evaporated milk, sweetened condensed milk, nonfat dry milk solids, half and half, sour half and half, acidified sour half and half, cultured sour half and half, concentrated milk and milk products, skim milk, reconstituted or recombined milk and milk products, low-fat milk, light milk, reduced fat milk, homogenized milk, frozen milk concentrate, eggnog, cultured milk, buttermilk, yogurt, cottage cheese, creamed cottage cheese, acidified milk, low-sodium milk, lactose-reduced milk, aseptically processed and packaged milk and milk products, milk with added safe and suitable microbial organisms, any other milk product, frozen dairy dessert or frozen dairy dessert mix, cheese or any other product designated as a milk product by the Commissioner made by the addition or subtraction of milkfat or addition of safe and suitable optional ingredients for protein, vitamin or mineral fortification.
Powdered dairy blends may be labeled Grade “A” and used as ingredients in Grade “A” dairy products, such as cottage cheese dressing mixes or starter cultures used to produce various Grade “A” cultured products, if they meet the requirements of this Rule. If used as an ingredient in Grade “A” products, such as those listed above, blends of dairy powders must be blended under conditions, which meet all applicable Grade “A” requirements. Grade “A” powder blend must be made from Grade “A” powdered dairy products, except that small amounts of functional ingredients, (total of all such ingredients shall not exceed 5% by weight of the finished blend) which are not Grade “A” are allowed in Grade “A” blends when the finished ingredient is not available in Grade “A” form, i.e. sodium caseinate. This is similar to the existing FDA position that such

dairy ingredient in small cans of freeze-dried starter culture need not be Grade "A".

~~54~~56. MILK TANK TRUCK - A "milk tank truck" is the term used to describe both a bulk milk pickup tanker and a milk transport tank.

~~55~~57. MILK TANK TRUCK CLEANING FACILITY – "Milk Tank Truck Cleaning Facility" means any place, premises, or establishment, separate from a milk plant, receiving or transfer station, where a milk tank truck is cleaned and sanitized.

~~56~~58. MILK TANK TRUCK DRIVER - A "milk tank truck driver" is any person who transports raw or pasteurized milk and milk products to or from a milk plant, receiving station or transfer station. Any transportation of a direct farm pickup requires the milk tank truck driver to have responsibility for accompanying official samples.

~~57~~59. MILK TRANSPORT TANK - A "milk transport tank" is a vehicle, including the truck and tank, used by the bulk milk hauler/sampler or milk tank truck driver to transport bulk shipments of milk from a milk plant, receiving station or transfer station to another milk plant, receiving station or transfer station.

~~58~~60. MILK TRANSPORTATION COMPANY - A "milk transportation company" is the company responsible for a milk tank truck(s).

~~59~~61. MISBRANDED MILK AND MILK PRODUCTS - A food shall be deemed to be misbranded -

(a) If its labeling is false or misleading and does not comply with Section XIV.

(b) If it is offered for sale under the name of another food.

(c) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(d) If its container is so made, formed, or filled as to be misleading.

(e) If in package form unless it bears a label containing:

(i) The name and place of business of the manufacturer, packer, or distributor; and

(ii) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: provided that, reasonable variations shall be permitted.

(f) If any word, statement, or other information required by or under authority of this rule to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms

as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed, unless:

(i) Its label bears the name of the food specified in the definition and standard, and, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

(h) If it purports to be or is presented as -

(i) A food for which a standard of quality has been prescribed by regulations as provided by Section 401 of the FD&C Act, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or

(ii) A food for which a standard or standards of fill of container have been prescribed and it falls below the standard of fill of container applicable thereto, unless its label bears a statement that it falls below such standard.

(i) If it is not subject to the provisions of paragraph (g) of this Section, unless its label bears:

(i) The common or usual name of the food, if any, and

(ii) In case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each.

(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Commissioner determines to be necessary in order fully to inform purchasers as to its value of such uses.

(k) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream. The provisions of this paragraph with respect to chemical preservatives shall not apply to a pesticide chemical when used in or on a raw agricultural commodity which is the produce of the soil.

(l) If it is a raw agricultural commodity which is the produce of the soil, bearing or containing a pesticide chemical applied after harvest, unless the shipping container of such commodity bears labeling which declares the presence of such chemical in or on such commodity and the common

or usual name and function of such chemical: provided, however, that no such declaration shall be required, while such commodity, having been removed from the shipping container, is being held or displayed for sale at retail out of such container in accordance with the custom of the trade.

(m) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive.

(n)

(i) If it contains saccharin, its label and labeling bear the following statement: 'USE OF THIS PRODUCT MAY BE HAZARDOUS TO YOUR HEALTH. THIS PRODUCT CONTAINS SACCHARIN WHICH HAS BEEN DETERMINED TO CAUSE CANCER IN LABORATORY ANIMALS'. Such statement shall be located in a conspicuous place on such label and labeling as proximate as possible to the name of such food and shall appear in conspicuous and legible type in contrast by typography, layout, and color with other printed matter on such label and labeling.

~~(o)~~ ~~(i)~~(ii) If it contains saccharin and is offered for sale, but not for immediate consumption, at a retail establishment, unless such retail establishment displays prominently, where such food is held for sale, notice (provided by the manufacturer of such food pursuant to subparagraph (ii)) for consumers respecting the information required by paragraph (n) to be on food labels and labeling.

~~(ii)~~(iii) Each manufacturer of food which contains saccharin and which is offered for sale by retail establishments but not for immediate consumption shall take such action as may be necessary to provide such retail establishments with the notice required by subparagraph (i).

~~60~~62. NONFAT YOGURT -

(a) Nonfat yogurt is the food produced by culturing one or more of the optional dairy ingredients specified in paragraph (c) of this Section with a characterizing bacterial culture that contains the lactic acid- producing bacteria, Lactobaccilus bulgaricus and Streptococcus thermophilus. One or more of the other optional ingredients specified in paragraph (b) and (c) of this Section may also be added. When one or more of the ingredients specified in paragraph (c)(i) of this Section are used, they shall be included in the culturing process. All ingredients used are safe and suitable. Nonfat yogurt, before the addition of bulky flavors, contains less than 0.5 percent milkfat and not less than 8.25 percent milk solids not fat, and has a titratable acidity of not less than 0.9 percent, expressed as lactic acid. The food may be homogenized and shall be pasteurized or ultra-pasteurized prior to the addition of the bacterial culture. Flavoring

ingredients may be added after pasteurization or ultra- pasteurization. To extend the shelf life of the food, nonfat yogurt may be heat-treated after culturing is completed, to destroy viable microorganisms.

(b) Vitamin addition (optional).

(i) if added, vitamin A shall be present in such quantity that each 946 milliliters (1- quart) of the food contains not less than 2000 International Units thereof, within limits of current good manufacturing practice.

(ii) if added, vitamin D shall be present in such quantity that each 946 milliliters (1-quart) of the food contains 400 International Units thereof within limits of good manufacturing practice.

(c) Optional dairy ingredients. Cream, milk, partially skimmed milk, used alone or in combination.

Other optional ingredients.

(i) Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food; provided, that the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present shall not be decreased as a result of adding such ingredients.

(ii) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or syrup form); brown sugar; refiner's syrup; molasses (other than blackstrap); high fructose corn syrup; fructose; fructose syrup; maltose; maltose syrup, dried maltose syrup; malt extract, dried malt extract; malt syrup, dried malt syrup; honey; maple sugar; or any other sweeteners listed in 21 CFR Part 168, except table syrup.

(iii) Flavoring ingredients.

(iv) Color additives.

(v) Stabilizers.

~~61~~63. NOT PASTEURIZED - “Not pasteurized” means any milk or milk product that has not been subjected to the temperature and time requirements of pasteurization using equipment designed for pasteurization or has not been aseptically processed and packaged. This does not apply to ~~farm cheese or to~~ cheese that has been aged at a temperature above 35°F for at least 60 days prior to sale.

~~62~~64. OFFICIALLY DESIGNATED LABORATORY - An “officially designated laboratory” is a commercial laboratory authorized to do official work by the

Department, or a milk industry laboratory officially designated by the Department for the examination of producer samples of Grade A raw milk for pasteurization and commingled milk tank truck samples of raw milk for drug residues and bacterial limits.

~~63~~65. OFFICIAL LABORATORY - An “official laboratory” is a biological, chemical or physical laboratory which is under the direct supervision of the Department.

~~64~~66. PASTEURIZATION - The terms "pasteurization", “pasteurized" and similar terms shall mean the process of heating every particle of milk or milk product in properly designed and operated equipment, to one of the temperatures given in the following chart and held continuously at or above that temperature for at least the corresponding specified time:

Temperature	**Time**
*63°C (145°F)	30 minutes
*72°C (161°F)	15 seconds
*89°C (191°F)	l.0 second
*90°C (194°F)	0.5 second
*94°C (201°F)	0.1 second
*96°C (204°F)	0.05 second
*100°C (212°F)	0.01 second

* If the fat content of the milk product is 10 percent or more, or if it contains added sweeteners, the specified temperature shall be increased by 3°C (5°F):

Provided, that eggnog shall be heated to at least the following temperature and time specifications:

Temperature	**Time**
69°C (155°F)	30 minutes
80°C (175°F)	25 seconds
83°C (180°F)	15 seconds

Provided further, that nothing in this definition shall be construed as barring any other pasteurization process which has been recognized by the U.S. Food and Drug Administration to be equally effective and which is approved by the Commissioner. Guidelines for properly designed and operated equipment may be found in the Grade A Pasteurized Milk Ordinance.

~~65~~67. PERSON - The word “person” shall include any individual, plant operator, partnership, corporation, company, firm, trustee, association or institution.

~~66~~68. PORTABLE/TEMPORARY MILKING PARLOR – A “portable/temporary milking parlor” is a mobile unit designed for occasional use.

~~67~~69. RAW MILK – See Definition “Not Pasteurized”.

~~68~~70. RECEIVING STATION - A “receiving station” is any place, premise or establishment where raw milk is received, collected, handled, stored or cooled and prepared for further transporting.

~~69~~71. RECONSTITUTED OR RECOMBINED MILK AND MILK PRODUCTS - “Reconstituted or recombined milk and/or milk products” shall mean milk or milk products defined in this section which result from reconstituting or recombining of milk constituents with potable water when appropriate.

~~70~~72. REDUCED FAT MILK –

(a) “Reduced fat milk” is milk that has less than or equal to 6 grams of fat per 8 ounce (240 mL) serving and contains not less than 8.25 percent milk solids not fat.

(b) Vitamin addition.

(i) Vitamin A shall be present in such quantity that each 964 milliliters (1 quart) of the food contains not less than 2,000 International Units thereof within limits of good manufacturing practice.

(ii) Addition of vitamin D is optional. If added, vitamin D shall be present in such quantity that each 946 milliliters (1 quart) of the food contains 400 International Units thereof within limits of good manufacturing practice.

~~71~~73. SANITIZATION – “Sanitization” is the application of any effective method or substance to a clean surface for the destruction of pathogens and other organisms as far as is practicable. Such treatment shall not adversely affect the equipment, the milk or milk product or the health of consumers, and shall be acceptable to the Department.

~~72~~74. SHEEP MILK – “Sheep milk” is the normal lacteal secretion practically free of colostrum, obtained by the complete milking of one or more healthy sheep. Sheep milk shall be produced according to the sanitary standards of this rule.

~~73~~75. SHERBET -

(a)

(i) “Sherbet” is a food produced by freezing, while stirring, a pasteurized mix consisting of one or more of the optional dairy ingredients specified in paragraph (b) of this Section, and may contain one or more of the optional caseinates specified in paragraph (c) of this Section subject to the conditions hereinafter set forth, and other safe and suitable nonmilk-derived ingredients; and excluding other food fats, except such as are added in small amounts to accomplish specific functions or are natural components of flavoring ingredients used. Sherbet is sweetened

with “SAFE AND SUITABLE SWEETENERS” and characterizing fruit ingredients specified in paragraph (d) of this Section or one or more of the non-fruit characterizing ingredients specified in paragraph (e) of this Section.

(ii) Sherbet weighs not less than 6 pounds to the gallon. The milkfat content is not less than 1 percent nor more than 2 percent, the nonfat milk derived solids content not less than 1 percent, and the total milk or milk-derived solids content is not less than 2 percent nor more than 5 percent by weight of the finished food. Sherbet that is characterized by a fruit ingredient shall have a titratable acidity, calculated as lactic acid, of not less than .35 percent.

(b) Optional dairy ingredients. The optional dairy ingredients referred to in paragraph (a) of this Section are:

Cream, dried cream, plastic cream (sometimes known as concentrated milk fat), butter, butter oil, milk, concentrated milk, evaporated milk, superheated condensed milk, sweetened condensed milk, dried milk, skim milk, concentrated skim milk, evaporated skim milk, condensed skim milk, sweetened condensed skim milk, sweetened condensed part-skim milk, nonfat dry milk, sweet cream buttermilk, condensed sweet cream buttermilk, dried sweet cream buttermilk, skim milk that has been concentrated and from which part of the lactose has been removed by crystallization, and whey and those modified whey products (e.g., reduced lactose whey, reduced minerals whey, and whey protein concentrate) that comply with 21 CFR Part 184. Water may be added, or water may be evaporated from the mix. The sweet cream buttermilk and the concentrated sweet cream buttermilk or dried sweet cream buttermilk, when adjusted with water to a total solids content of 8.5 percent, has a titratable acidity of not more than 0.17 percent, calculated as lactic acid. The term "milk" as used in this section means cow’s milk.

(c) Optional caseinates. The optional caseinates referred to in paragraph (a) of this Section which may be added to sherbet mix are: casein prepared by precipitation with gums, ammonium caseinate, calcium caseinate, potassium caseinate, and sodium caseinate. Caseinates may be added in liquid or dry form, but must be free of excess alkali; such caseinates are not considered to be milk solids.

(d) Optional fruit-characterizing ingredients. The optional fruit characterizing ingredients referred to in paragraph (a) of this Section are any mature fruit or the juice of any mature fruit. The fruit or fruit juice used may be fresh, frozen, canned, concentrated, or partially or wholly dried. The fruit may be thickened with pectin or other optional ingredients. The fruit is prepared by the removal of pits, seeds, skins, and cores, where such removal is usual in preparing that kind of fruit for consumption as fresh fruit. The fruit may be screened, crushed, or otherwise comminuted. It may be acidulated. In the case of concentrated fruit or fruit juices, from which part of the water is removed, substances contributing flavor volatilized during water

removal may be condensed and reincorporated in the concentrated fruit or fruit juice. In the case of citrus fruits, the whole fruit, including the peel but excluding the seeds, may be used, and in the case of citrus juice or concentrated citrus juices, cold-pressed citrus oil may be added thereto in an amount not exceeding that which would be obtained if the whole fruit had been used. The quantity of fruit ingredients used is such that, in relation to the weight of the finished sherbet, the weight of fruit or fruit juice, as the case may be (including water necessary to reconstitute partially or wholly dried fruits or fruit juices to their original moisture content), is not less than 2 percent in the case of citrus sherbets, 6 percent in the case of berry sherbets, and 10 percent in the case of sherbets prepared with other fruits. For the purpose of this Section, tomatoes and rhubarb are considered as kinds of fruit.

(e) Optional non-fruit characterizing ingredients. The optional non-fruit characterizing ingredients referred to in paragraph (a) of this Section include but are not limited to the following:

(i) Ground spice or infusion of coffee or tea.

(ii) Chocolate or cocoa, including syrup.

(iii) Confectionery.

(iv) Distilled alcoholic beverage, including liqueurs or wine, in an amount not to exceed that required for flavoring the sherbet.

(v) Any natural or artificial food flavoring (except any having a characteristic fruit or fruit-like flavor).

(f) Nomenclature.

(i) The name of each sherbet is as follows:

(a) The name of each fruit sherbet is “_____ sherbet", the blank being filled in with the common name of the fruit or fruits from which the fruit ingredients used are obtained. When the names of two or more fruits are included, such names shall be arranged in order of predominance, if any, by weight of the respective fruit ingredients used.

(b) The name of each non-fruit sherbet is “_____ sherbet", the blank being filled in with the common or usual name or names of the characterizing flavor or flavors; for example, “peppermint”, except that if the characterizing flavor used is vanilla, the name of the food is “_____ sherbet”, the blank being filled in as specified by Section I(A)(37)(e)(ii) and (v)(a).

(ii) When the optional ingredients, artificial flavoring, or artificial coloring are used in sherbet, they shall be named on the label as follows:

(a) If the flavoring ingredient or ingredients consists exclusively of artificial flavoring, the label designation shall be "artificially flavored".

(b) If the flavoring ingredients are a combination of natural and artificial flavors, the label designation shall be “artificial and natural flavoring added".

(c) The label shall designate artificial coloring by the statement "artificially colored", “artificial coloring added", "with added artificial coloring", or “_____, and artificial color added", the blank being filled in with the name of the artificial coloring used.

(g) Characterizing flavor(s). Wherever there appears on the label any representation as to the characterizing flavor or flavors of the food and such flavor or flavors consist in whole or in part of artificial flavoring, the statement required in paragraph (f) (ii)(a) and (b) of this Section, as appropriate, shall immediately and conspicuously precede or follow such representation, without intervening written, printed, or graphic matter (except that the word "sherbet" may intervene) in a size reasonably related to the prominence of the name of the characterizing flavor and in any event the size of the type is not less than 6-point on packages containing less than 1 pint, not less than 8-point on packages containing at least 1 pint but less than one-half gallon, not less than 10 point on packages containing at least one-half gallon but less than 1 gallon, and not less than 12 point on packages containing 1 gallon or over.

(h) Display of statements required in paragraph (f)(ii). Except as specified in paragraph (g) of this Section, the statements required by paragraph (f)(ii) of this Section shall be set forth on the principal display panel or panels of the label with such prominence and conspicuousness as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(i) Label declarations. Each of the optional ingredients used shall be declared on the label, as required in Section XIV.

~~74~~76. SKIM, FAT-FREE, NONFAT MILK –

(a) “Skim, fat-free, nonfat milk” is milk that has less than 0.5 grams of fat per 8 ounce (240mL) serving and contains not less than 8.25 percent milk solids not fat.

(b) Vitamin addition.

(i) Vitamin A shall be present in such quantity that each 946 milliliters (1 quart) of the food contains not less than 2,000 International Units thereof within limits of good manufacturing practice.

(ii) Addition of vitamin D is optional. If added, vitamin D shall be present in such quantity that each 946 milliliters (1 quart) of the food contains 400 International Units thereof within limits of good manufacturing practice.

~~75~~77. SOUR CREAM OR CULTURED SOUR CREAM -

(a) "Sour cream" results from the souring, by lactic acid producing bacteria, of cream. Sour cream contains not less than 18 percent milkfat; except that when the food is characterized by the addition of nutritive sweeteners or bulky flavoring ingredients, the weight of the milkfat is not less than 18 percent of the remainder obtained by subtracting the weight of such optional ingredients from the weight of the food; but in no case does the food contain less than 14.4 percent milkfat. Sour cream has a titratable acidity of not less than 0.5 percent, calculated as lactic acid.

(b) Optional ingredients.

(i) Safe and suitable ingredients that improve texture, prevent syneresis, or extend the shelf life of the product.

(ii) Sodium citrate in an amount not more than 0.1 percent may be added prior to culturing as a flavor precursor.

(iii) Rennet.

(iv) Safe and suitable nutritive sweeteners.

(v) Salt.

(vi) Flavoring ingredients, with or without safe and suitable coloring, as follows:

(a) Fruit and fruit juice (including concentrated fruit and fruit juice).

(b) Safe and suitable natural and artificial food flavoring.

~~76~~78. SOUR HALF-AND-HALF OR CULTURED SOUR HALF-AND-HALF -

(a) "Sour half-and-half" results from the souring, by lactic acid producing bacteria, of pasteurized half-and-half. Sour half-and-half contains not less than 10.5 percent but less than 18 percent milkfat; except that when the food is characterized by the addition of nutritive sweeteners or bulky flavoring ingredients, the weight of the milkfat is not less than 10.5 percent of the remainder obtained by subtracting the weight of such optional ingredients from the weight of the food; but in no case does the food contain less than 8.4 percent milkfat. Sour half-and-half has a titratable acidity of not less than 0.5 percent, calculated as lactic acid.

(b) Optional ingredients.

(i) Safe and suitable ingredients that improve texture, prevent syneresis, or extend the shelf life of the product.

(ii) Sodium citrate in an amount not more than 0.1 percent may be added prior to culturing as a flavor precursor.

(iii) Rennet.

(iv) Safe and suitable nutritive sweeteners.

(v) Salt.

(vi) Flavoring ingredients, with or without safe and suitable coloring, as follows:

(a) Fruit and fruit juice (including concentrated fruit and fruit juice).

(b) Safe and suitable natural and artificial food flavoring.

(vii) Safe and suitable coloring.

~~77~~79. STERILIZED - The term "sterilized" when applied to piping, equipment and containers used for milk and milk products shall mean the condition achieved by the application of heat, chemical sterilant(s) or other appropriate treatment that renders the piping, equipment and containers free of viable microorganisms.

~~78~~80. TRANSFER STATION - A "transfer station" is any place, premises or establishment where milk or milk products are transferred directly from one milk tank truck to another.

~~79~~81. ULTRA-PASTEURIZED - The term "ultra-pasteurized", when used to describe a dairy product, means that such product shall have been thermally processed at or above 138°C (280°F) for at least 2 seconds, either before or after packaging, so as to produce a product that has an extended shelf life under refrigerated conditions.

82. WATER BUFFALO – Water buffalo milk is the normal lacteal secretion, practically free of colostrums, obtained by the complete milking of one (1) or more healthy water buffalo. Water buffalo milk shall be produced according to the sanitary standards of this Rule. The word "milk" shall be interpreted to include water buffalo milk.

~~80~~83. WHIPPED CREAM – "Whipped cream" is heavy cream or light whipping cream into which air or gas has been incorporated.

~~81~~84. WHIPPED LIGHT CREAM – "Whipped light cream" is light cream into which air or gas has been incorporated.

~~82~~85. YOGURT -

(a) "Yogurt" is the food produced by culturing one or more of the optional dairy ingredients specified in paragraph (c) of this Section with a characterizing bacterial culture that contains the lactic acid-producing bacteria Lactobacillus bulgaricus and Streptococcus thermophilus. One or more of the other optional ingredients specified in paragraph (b) and (d) of this Section may also be added. When one or more of the ingredients specified in paragraph (d)(i) of this Section are used, they shall be included in the culturing process. All ingredients used are safe and suitable. Yogurt, before the addition of bulky flavors, contains not less than 3.25 percent milkfat and not less than 8.25 percent milk solids not fat, and has a titratable acidity of not less than 0.9 percent, expressed as lactic acid. The food may be homogenized and may be pasteurized or ultra-pasteurized prior to the addition of the bacterial culture. Flavoring ingredients may be added after pasteurization or ultra- pasteurization. To extend the shelf life of the food, yogurt may be heat treated after culturing is completed, to destroy viable microorganisms.

(b) Vitamin addition (optional).

(i) if added, vitamin A shall be present in such quantity that each 946 milliliters (1-quart) of the food contains not less than 2,000 International Units thereof within limits of current good manufacturing practice.

(ii) If added, vitamin D shall be present in such quantity that each 946 milliliters (1-quart) of the food contains 400 International Units thereof, within limits of current good manufacturing practice.

(c) Optional dairy ingredients: Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.

(d) Other optional ingredients.

(i) Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food: provided, that the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present shall not be decreased as a result of adding such ingredients.

(ii) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or syrup form); brown sugar; refiner's syrup; molasses (other than blackstrap); high fructose corn syrup; fructose; fructose syrup; maltose; maltose syrup, dried maltose syrup; malt extract, dried malt extract; malt syrup, dried malt syrup; honey; maple sugar; or any other sweeteners listed in 21 CFR Part 168, except table syrup.

(iii) Flavoring ingredients.

(iv) Color additives.

(v) Stabilizers.

SECTION II - ADULTERATED OR MISBRANDED MILK OR MILK PRODUCTS

No person shall, within the State of Maine, produce, provide, sell, offer, or expose for sale or have in possession with intent to sell any milk or milk product which is adulterated or misbranded. Provided, that in an emergency, the sale of milk and milk products which have not been graded, or the grade of which is unknown, may be authorized by the Department in which case such products shall be labeled “ungraded”.

Any adulterated or misbranded milk or milk product shall be impounded by the Department and disposed of in accordance with applicable laws or rules.

SECTION III - LICENSING AND PERMITS

A. Licensing of Milk Distributors.

No milk distributor shall sell milk or milk products without first obtaining a license from the commissioner. The commissioner shall prescribe the form of the license. The license shall be applied for annually on or before the first day of January in each year, except for wholesale manufacturers of frozen dairy desserts who shall apply on or before the first day of June. Each licensee shall comply with all applicable State and Federal laws and rules. A satisfactory inspection shall be required before issuance of a license to milk distributors.

B. Milk Distributor License Fee Schedule.

Annual sales or distribution over 25 million pounds - $300.00
Annual sales or distribution of 10-25 million pounds - $150.00
Annual sales or distribution of 1-10 million pounds - $100.00
Annual sales or distribution of 100,000 to 1 million pounds - $50.00
Annual sales or distribution of less than 100,000 pounds $25.00

Sales and distribution of milk and/or milk products are for within the State of Maine only.

C. Permits

~~1. Milk Producer - Every milk producer shall hold a permit issued by the Commissioner. There is no fee for a permit.~~

~~Only a person who complies with the requirements of this rule shall be entitled to receive and retain such a permit. Permits shall not be transferable with respect to persons and/or locations.~~

~~A milk producer who holds a permit shall operate his/her dairy farm or portable/temporary milking parlor in substantial compliance with the provisions of this rule.~~

~~2. Milk Sampling, Hauling and Transportation~~

~~(a) All bulk milk hauler/samplers based in Maine must obtain a permit from the Department.~~

~~(b) Dairy plant samplers are not required to hold a permit from the Department but are evaluated every two years by the State Sampling Surveillance Officer.~~

~~(c) Milk tank truck drivers are not required to hold a permit from the State.~~

~~(d) Receiving stations, milk tank truck cleaning facilities, and transfer stations must obtain a permit from the Department.~~

~~(e) Milk transportation companies based in Maine must obtain a permit from the Department.~~

Every milk producer, bulk milk hauler and sampler, milk transportation company, receiving station, transfer station and portable/temporary milking parlor shall hold a valid permit in accordance with the requirements of this rule and state law. A permit may be suspended for any failure to comply with these requirements. Permits are issued at no cost and are not transferable between person, businesses or farms.

Permits are issued to:

1. Milk Producer: A permit authorizes the milk producer to ship, sell and/or receive milk

2. Bulk Milk Hauler/Sampler: A permit authorizes the bulk milk hauler/sampler to collect official samples and/or transport raw milk from a farm and/or raw milk products to or from a farm, milk plant, receiving station or transfer station.

3. Receiving stations: A permit authorizes the receiving station to receive, collect, handle, store or cool and prepare raw milk for further transporting.

4. Milk Tank Truck Cleaning Facilities: A permit authorizes the milk tank truck cleaning facility to clean and sanitize a milk tank truck.

5. Transfer Stations: A permit authorizes a transfer station to transfer milk or milk products directly from one milk tank truck to another.

6. Milk Transportation Company: A permit authorizes the milk transportation company to transport raw milk in a milk transport tank driven by a milk tank truck driver. Milk tank truck drivers are not required to obtain individual permits.

7. Portable/temporary milking parlor: A permit authorizes the operator of a portable/temporary milking parlor to ship, sell or receive milk.

SECTION IV - INSPECTION

Single service container manufacturers and each dairy farm, milk plant, receiving station and transfer station whose milk or milk products are intended for consumption, and each milk hauler who collects samples of raw milk for pasteurization, for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, receiving station or transfer station and ~~his/her~~ their bulk milk pickup tank and its appurtenances shall be inspected by the Department. The Department shall:

A. Inspect each bulk milk pickup tanker and its appurtenances, used by a milk hauler who collects samples of raw milk for pasteurization for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, receiving station or transfer station, at least every 12 months;

1. A copy of the current inspection report shall accompany the bulk milk pickup tanker at all times.

2. When significant defects or violations are encountered by the Department or another State's regulatory authority, a copy of that report shall be forwarded to the Department and also carried on the bulk milk pickup tanker until the violations are corrected.

3. Bulk milk pickup tanker inspection shall be conducted in a suitable location, i.e. a dairy plant, receiving station or transfer station or milk tank truck cleaning

facility. When significant cleaning, construction or repair defects are noted, the bulk milk pickup tanker shall be removed from service until proper confined entry safety requirements can be satisfied to determine cleaning or repairs needed. A qualified individual to the satisfaction of the Department may verify cleaning and repairs.

4. Inspection reports completed by regulatory authorities other than the Department shall be forwarded to the Department for verification of annual inspection as required by this section and the Department may use these reports to satisfy permit requirements.

B. Inspect each ~~dairy~~ industry plant sampler, bulk milk hauler/samplers' pickup and sampling procedures at least once every 24 months;

C. Inspect each milk plant, milk equipment and receiving station at least once every 3 months;

D. Inspect each transfer station, and milk tank truck cleaning facility at least once very 6 months; and

E. Inspect each dairy farm at least once every 6 months.

F. Inspect each portable/temporary milking parlor whenever it changes location.

G. Inspect seasonal frozen dairy dessert manufacturers at least once every 12 months.

H. Should the violation of any requirement set forth in this Section, or in the case of a milk hauler/sampler or industry plant sampler also Section VI, be found to exist on an inspection, a second inspection shall be required after the time deemed necessary to remedy the violation, but not before 3 days. This second inspection shall be used to determine compliance with requirements of Section IV or in the case of a milk hauler/sampler or industry plant sampler also Section VI. Any violation of the same requirement of Section IV, or in the case of a milk hauler/sampler or industry plant sampler also Section VI on such second inspection, shall in the case of a milk hauler/sampler call for permit suspension in accordance with 7 M.R.S.A § 2902-A or in the case of an industry plant sampler, shall require that the collection of official regulatory samples be ceased until the industry plant sampler has been successfully re-trained and re-evaluated by the Department.

I. When the Department finds that a critical processing element violation involving:

(i) Proper pasteurization, whereby every particle of milk or milk product may not have been heated to the proper temperature and held for the required time in properly designed and operated equipment; or

(ii) A cross-connection, whereby direct contamination of pasteurized milk or milk product is occurring; or

(iii) Direct contamination of pasteurized milk or milk product is occurring, the Department shall take immediate action to prevent further processing of such milk or milk products until such violations of critical processing elements have been corrected. Should correction of such violative processing elements not be accomplished immediately, the Department shall take prompt action to suspend the license.

J. When an inspection of a milk plant producing aseptically processed milk and milk products reveals that the process used has not met the requirements of aseptic processing as defined in 21 CFR 113, it shall be considered an imminent hazard to public health and the Department shall take immediate action to suspend the license of the plant.

K. Inspect single service container manufacturers at least once every 6 months.

L. One copy of the inspection report shall be handed to the operator or other responsible person, or be posted in a conspicuous place on an inside wall of the establishment. Said inspection report shall not be defaced and shall be made available to the Department upon request. An identical copy of the inspection report shall be filed with the records of the Department.

M. Every milk producer, hauler, distributor or plant operator shall, upon request of the Department, permit access of officially designated persons to all parts of the establishment or facilities to determine compliance with the provisions of the rule. A distributor or plant operator shall furnish the Department, upon request, for official use only, a true statement of the actual quantities of milk and milk products of each grade purchased and sold, a list of all sources of such milk and milk products, records of inspection, tests, pasteurization time and temperature records.

SECTION V - STANDARDS FOR MILK AND MILK PRODUCTS

All Grade A raw milk for pasteurization, ultra-pasteurization or aseptic processing and all Grade A pasteurized, ultra-pasteurized or aseptically processed milk and milk products shall be produced, processed, and pasteurized, ultra-pasteurized or aseptically processed to conform with the following chemical, bacteriological and temperature standards, and the sanitation requirements of Section VI. Milk and milk products not pasteurized, shall be produced and processed to conform with the following chemical, bacteriological and temperature standards, and the sanitation requirements of Section VI.

No process or manipulation other than pasteurization, ultra-pasteurization or aseptic processing and appropriate refrigeration shall be applied to milk and milk products for the purpose of removing or deactivating microorganisms. Milk for aged cheese is exempt from this requirement. Provided, that in the bulk shipment of cream, skim milk or low-fat milk, the heating of the raw milk, one time, to temperatures greater than 52°C (125°F), but less than 72°C (161°F), for separation purposes is permitted when the resulting bulk shipments of cream, skim milk or low-fat milk are labeled heat-treated. In the case of heat-treated cream, the cream may be further heated to

less than 75°C (166°F) in a continuing heating process and immediately cooled to 7°C (45°F) or less when necessary for enzyme deactivation (such as lipase reduction) for a functional reason.

TABLE 1. CHEMICAL, BACTERIOLOGICAL AND TEMPERATURE STANDARDS

RAW MILK AND MILK PRODUCTS FOR PASTEURIZATION, ULTRA-PASTEURIZATION OR ASEPTIC PROCESSING	Temperature.....	Cooled to 7 °C(45°F) or less within two hours after milking: provided, that the blend temperature after the first and subsequent milkings does not exceed 10°C (50°F).
	Bacterial limits.....	Individual producer milk not to exceed 100,000 per ml prior to commingling with other producer milk. Not to exceed 300,000 per ml as commingled milk prior to pasteurization.
	Drugs	No positive results on drug residue detection methods as referenced in Section XII – ~~The examination of Milk and milk products~~ Methods of Analysis.
	Somatic Cell Count*...	Individual producer milk: Not to exceed 750,000 per ml.
PASTEURIZED MILK AND MILK PRODUCTS AND BULK SHIPPED HEAT-TREATED MILK PRODUCTS	Temperature.....	Cooled to 7°C(45°F) or less and maintained thereat.
	Bacterial limits**....	20,000 per ml.
	Coliform***.....	Not to exceed 10 per ml. Provided, that in the case of bulk milk transport tank shipments, shall not exceed 100 per ml.
	Phosphatase***.....	~~Less than 1 microgram per ml by the Scharer Rapid Method.~~ Less than 350 milliunits/L for fluid products and ~~less than 500 for~~ other milk products by the Flourometer or Charm ALP or equivalent.
	Drugs**.....	No positive results on drug residue detection methods as referenced in Section XII~~-The examination of milk and milk products~~ Methods of Analysis which have been found to be acceptable for use with pasteurized and heat-treated milk and milk products.
ASEPTICALLY PROCESSED MILK AND MILK PRODUCTS	Temperature.....	None
	Bacterial limits.....	No growth by test specified in Section XII.
	Drugs**.....	No positive results on drug residue detection methods as referenced in Section XII~~-The examination of milk and milk products~~ Methods of Analysis which have been found to be acceptable for use with aseptically processed milk and milk products.

TABLE 1. CHEMICAL, BACTERIOLOGICAL AND TEMPERATURE STANDARDS (Continued)

MILK AND MILK PRODUCTS (NOT PASTEURIZED) SOLD TO CONSUMERS	Temperature	Cooled to 7°C(45°F) or less and maintained
	Bacterial limits**	50,000 per ml.
	Coliform***	Not to exceed 10 per ml.
	Drugs**	No positive results on drug residue detection Methods as referenced in Section XII ~~The examination of milk and milk products~~ Methods of Analysis which have been found to be acceptable for use with not pasteurized milk and milk products.
AGED CHEESE	Temperature	Aged cheese shall be aged at a temperature above 35°F.
SINGLE SERVICE CONTAINER MANUFACTURERS	Bacterial limits	The residual bacteria count shall not exceed 50 per container, except that in containers less than 100 mL, the count shall not exceed ten (10) colonies.
	Coliform	0 coliform
Multi use containers	Bacterial limits	The residual bacteria count shall not exceed 1 per mL of capacity.
	Coliform	0 coliform
WATERS: Source Water	Coliform	<1 by MMO-MUG Presence/Absence Method
Recirculating Water	Coliform	<1.1 by Most Probable Number Method

*Goat Milk 1,000,000/ml, Sheep Milk 750,000/ml
**Not Applicable to acidified or cultured products.
***Not applicable to bulk shipped heat-treated milk products.

SECTION VI - SANITATION REQUIREMENTS FOR PRODUCTION AND PROCESSING

A. SANITATION REQUIREMENTS FOR DAIRY FARMS – Guidelines for determining compliance with these requirements may be found in the Grade A Pasteurized Milk Ordinance.

1. ABNORMAL MILK - ~~Cows~~ Lactating animals which show evidence of the secretion of ~~abnormal~~ milk with abnormalities in one or more quarters, based upon bacteriological, chemical or physical examination, shall be milked last or with separate equipment and the milk shall be discarded. ~~Cows~~ Lactating animals producing abnormal milk, that is lactating animals which have been treated with, or ~~cows which~~ have consumed chemical, medicinal or radioactive agents which are capable of being secreted in the milk and which, in the judgment of the Department, may be deleterious to human health, shall be milked last or with separate equipment and the milk disposed of as the Department may direct. For applicability to Automatic Milking Installations refer to Appendix Q, 2003 Pasteurized Milk Ordinance.

2. MILKING BARN, STABLE OR PARLOR--CONSTRUCTION - A milking barn, stable or parlor shall be provided on all dairy farms. The area used for milking purposes shall:

(a) Have floors constructed of concrete or equally impervious materials.

(b) Have walls and ceilings which are constructed of smooth material, be in good repair, dust tight, and be painted or finished in an approved manner;

(c) Have separate stalls or pens for horses, calves and bulls;

(d) Be provided with natural and/or artificial light, well distributed, for day and/or night milking;

(e) Provide sufficient air space and air circulation to prevent condensation and excessive odors.

(f) Properly prepared plans for milking equipment installation in all milking facilities, milk plants, receiving stations and transfer stations regulated under this rule which are hereinafter constructed may be submitted to the Department. Equipment standards set forth in “3-A Accepted Practices for the Design, Fabrication and Installation of Milk Handling Equipment” may be used as a guideline.

3. MILKING BARN, STABLE OR PARLOR--CLEANLINESS - The interior shall be kept clean. Floors, walls, ceilings, windows, pipelines and equipment shall be free of filth and/or litter and shall be clean. Swine and fowl shall be kept out of the milking facility.

Feed shall be stored in such a manner that will not increase the dust content of the air or interfere with the cleaning of the floor.

Surcingles, milk stools and antikickers shall be kept clean and stored above the floor.

4. COWYARD - The cowyard shall be graded to drain and shall have no standing pools of water or accumulations of organic wastes. Provided, that in loafing or cattle-housing areas, cow droppings and soiled bedding shall be removed, or clean bedding added, to prevent the soiling of the cow's udder and flanks. Cooling ponds shall be allowed provided they are constructed and maintained in a manner that does not result in the visible soiling of flanks, udders, bellies and tails of lactating animals exiting the pond. Waste feed shall not be allowed to accumulate. Manure packs shall be properly drained and shall provide a reasonably firm footing. Swine shall be kept out of the cowyard.

   Nutrient Management Plans shall be required unless exempted by Maine law or Department Nutrient Management Rules, Chapter 565 for a person who owns or operates a farm if it meets one or more of the following criteria:

   (a) The farm confines and feeds 50 or more animal units at any one time;

   (b) The farm utilizes more than 100 tons of manure per year not generated on that farm;

   (c) The farm is the subject of a verified complaint of improper manure handling;

   (d) The farm stores or utilizes regulated residuals.

   Nutrient Management Plans shall be implemented in accordance with 7 M.R.S.A. Chapter 747, Nutrient Management Act.

5. MILKHOUSE OR ROOM--CONSTRUCTION AND FACILITIES - A milkhouse or room of sufficient size shall be provided, in which the cooling, handling and storing of milk and the washing, sanitizing and storing of milk containers and utensils shall be conducted.

   (a) The milkhouse shall be provided with a smooth floor constructed of concrete or equally impervious material, graded to drain and maintained in good repair. Liquid waste shall be disposed of in a sanitary manner. Floor drains shall be accessible and shall be trapped if connected to a sanitary sewer system.

   (b) The walls and ceilings shall be constructed of smooth material, be in good repair, dust tight, and be painted or finished in an approved manner.

   (c) The milkhouse shall have adequate natural and/or artificial light and be well ventilated.

(d) The milkhouse shall be used for no other purpose than milkhouse operations. There shall be no direct opening into living quarters or milking facility. Provided, that a direct opening between the milkhouse and milking barn, stable or parlor is permitted when a tight-fitting, self-closing, solid door(s) hinged to be single or double acting is provided. Screened vents in the wall between the milkhouse and a breezeway, which separates the milkhouse from the milking parlor, are permitted, provided animals are not housed within the milking facility.

(e) Water under pressure shall be piped into the milkhouse.

(f) The milkhouse shall be equipped with a two-compartment wash vat and adequate hot water heating facilities.

(g) When a transportation tank is used for the cooling and/or storage of milk on the dairy farm, such tank shall be provided with a suitable shelter for the receipt of milk. Such shelter shall be adjacent to, but not a part of, the milkroom and shall comply with the requirements of the milkroom with respect to construction, light, drainage, insect and rodent control and general maintenance.

(h) The milkroom shall be provided with a hoseport conveniently located for use by milk haulers when applicable. The hoseport must be constructed and maintained as to prevent insect and rodent entry.

6. MILKHOUSE OR ROOM--CLEANLINESS - The floors, walls, ceiling, windows, tables, shelves, cabinets, wash vats, non-product contact surfaces of milk containers, utensils and equipment and other milkroom equipment shall be clean. Only articles directly related to milkroom activities shall be permitted in the milkroom. The milkroom shall be free of trash, animals and fowl.

7. TOILET - Every dairy farm shall be provided with one or more toilets, conveniently located, properly constructed, operated and maintained in a sanitary manner. The waste shall be inaccessible to flies and shall not pollute the surface or contaminate any water supply. Tight fitting, self-closing, solid door must be provided to separate the toilet room from the milkroom.

8. WATER SUPPLY - Water for milkhouse and milking operations shall be from a supply properly located, protected and operated and shall be easily accessible, adequate and of a safe, sanitary quality.

9. UTENSILS AND EQUIPMENT--CONSTRUCTION - All multi-use containers, equipment and utensils used in the handling, storage or transportation of milk shall be made of smooth, nonabsorbent, corrosion-resistant, nontoxic materials, and shall be so constructed as to be easily cleaned. All containers, utensils and equipment shall be in good repair. Multiple-use woven material shall not be used for straining milk. All single-serve articles shall have been manufactured, packaged, transported and handled in a sanitary manner and shall comply with the applicable requirements of (B)(14) of this section. Articles intended for single-service use shall not be reused. Farm holding/cooling tanks, welded

sanitary piping and transportation tanks shall comply with the applicable requirements of (B)(10) and (B)(11) of this section.

10. UTENSILS AND EQUIPMENT--CLEANING - The product-contact surfaces of all multi-use containers, equipment and utensils used in the handling, storage or transportation of milk shall be cleaned after each usage.

11. UTENSILS AND EQUIPMENT – SANITATION – The product-contact surfaces of all multi-use containers, equipment and utensils used in the handling, storage or transportation of milk shall be sanitized before each usage.

12. UTENSILS AND EQUIPMENT--STORAGE - All containers, utensils and equipment used in the handling, storage or transportation of milk, unless stored in sanitizing solutions, shall be stored to assure complete drainage and shall be protected from contamination prior to use. Provided, the pipeline milking equipment such as milker claws, inflations, weigh jars, meters, milk hoses, milk receivers, tubular coolers, plate coolers and milk pumps which are designed for mechanical cleaning and other equipment, as accepted by FDA which meets these criteria, may be stored in the milking barn or parlor, provided this equipment is designed, installed and operated to protect the product and solution-contact surfaces from contamination at all times. Single service articles (filters) are to be stored free of contamination. Provided, in the case of a milking parlor that opens directly into an enclosed housing area, through a covered holding area, the holding area may be seasonally enclosed when:

- There are no manure pit openings in the parlor, holding area or in the housing area close enough to affect the milking parlor.
- The cattle holding and housing areas are maintained in good repair and reasonably clean.
- With respect to dust, odors, rodents and insects, the entire area meets milking parlor standards and the parlor is free of evidence of birds.

13. MILKING--FLANKS, UDDERS AND TEATS - Milking shall be done in a milking barn, stable or parlor. Flanks, udders, bellies and tails of all milking cows shall be free from visible dirt. All brushing shall be completed prior to milking. The udders and teats of all milking cows shall be clean and dry before milking. Teats shall be treated with a sanitizing solution just prior to the time of milking and shall be dry before milking. Provided that the sanitizing of teats shall not be required if the udder is dry and the teats have been thoroughly cleaned (not dry wiped) and dried (manually wiped dry) prior to milking. Wet hand milking is prohibited.

14. PROTECTION FROM CONTAMINATION - Milking equipment and milkhouse facilities shall be located and operated to prevent any contamination of milk, equipment, containers and utensils. No milk shall be strained, poured, transferred or stored unless it is properly protected from contamination.

After sanitization, all containers, utensils and equipment shall be handled in such a manner as to prevent contamination of any product-contact surface.

Vehicles used to transport milk from the dairy farm to the milk plant, receiving station or transfer station shall be constructed and operated to protect their contents from the sun, freezing and contamination. Such vehicles shall be kept clean, inside and out, and no substance capable of contaminating the milk shall be transported.

15. DRUG AND CHEMICAL CONTROL - Effective measures shall be taken to prevent the contamination of milk, containers, equipment, and utensils by cleaners and sanitizers, drugs and drug administrating equipment.
    a. Lactating animals treated with medicinal agents must be:
        1. Identified, i.e. leg bands, chalk marks, etc.; and/or
        2. Segregated; or
        3. Otherwise handled in a manner such as to preclude the adulteration of milk offered for sale.
    b. Treatment Records (which may consist of paper and file folders, card files, appointment book type calendars, monthly calendars, chalk boards (temporary records), electronic computer records, etc) must include the following information:
        1. Identity of the animal (s) treated;
        2. Date(s) of treatment;
        3. Drug(s) or other chemicals administered;
        4. Dosage administered;
        5. Milk discard time; and
        6. Withdrawal time prior to slaughter, even if zero.

    c. Maintenance of Records: The proper use or misuse of some animal drugs may cause prolonged residues in milk (4 to 45 days) and meat (18 to 24 months). Verification of drug treatment records may be necessary in the event of an investigation or trace back by the industry or Department to identify specific treated animal(s) that may be related to a milk or dairy beef residue. Producers must maintain all treatment records for a minimum of two (2) years in the event of a need to trace back or follow up on a confirmed milk or meat residue.
    d. Treated animal must be quarantined or segregated, or otherwise handled in manner to preclude the sale of milk or the offering of treated animals for sale for slaughter prior to the end of the prescribed withdrawal time
    e. Farm personnel involved in the treatment of animals must be educated on proper drug use and methods to avoid the marketing of adulterated milk or meat for human food

16. PERSONNEL--HAND-WASHING FACILITIES - Adequate hand-washing facilities shall be provided, including a lavatory fixture with hot and cold or warm running water, soap or detergent and individual sanitary towels, convenient to the milking facility and flush toilet.

17. PERSONNEL--CLEANLINESS - Hands shall be washed clean and dried with an individual sanitary towel immediately before milking, before performing any milkhouse function and immediately after the interruption of any of these

activities. Milkers and milk haulers shall wear clean outer garments while milking or handling milk, milk containers, utensils, or equipment.

18. COOLING - Raw milk for pasteurization shall be cooled to 7°C(45°F) or less within 2 hours after milking. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10°C (50°F). All farm bulk milk tanks manufactured after January 1, 2000 shall be equipped with an approved temperature-recording device.

19. INSECT AND RODENT CONTROL - Effective measures shall be taken to prevent the contamination of milk, milking equipment by insects and rodents and by chemicals used to control vermin. Milkrooms shall be free of insects and rodents. Surroundings shall be kept neat, clean and free of conditions which might harbor or be conducive to the breeding of insects and rodents. Feed shall be stored in such a manner that it will not attract birds, rodents or insects.

20. Requirements for Automatic Milking Installations can be found in Appendix Q, 2003 Pasteurized Milk Ordinance.

B. SANITATION REQUIREMENTS FOR PASTEURIZED, ULTRA- PASTEURIZED, ASEPTICALLY PROCESSED MILK AND MILK PRODUCTS – Guidelines for determining compliance with these requirements may be found in the Grade A Pasteurized Milk Ordinance.

A receiving station shall comply with (B)(1) to (B)(15), inclusive, and (B)(17), (B)(20) and (B)(22), except that the partitioning requirement of (B)(5) shall not apply.

A transfer station shall comply with (B)(1), (B)(4), (B)(6), (B)(7), (B)(8), (B)(9), (B)(10), (B)(11), (B)(12), (B)(14), (B)(15), (B) 17, (B)(20) and (B)(22), and as climatic and operating conditions require, the applicable provisions of (B)(2) and (B)(3). Provided, that in every case, overhead protection shall be provided. Facilities for the cleaning and sanitizing of milk tank trucks shall comply with (B)(1), (B)(4), (B)(6), (B)(7), (B)(8), (B)(9), (B)(10), (B)(11), (B)(12), (B)(14), (B)(15), (B)(20), and (B)(22), and as climatic and operating conditions require, the applicable provisions of (B)(2) and (B)(3). Provided, that in every case, overhead protection shall be provided.

1. FLOORS--CONSTRUCTION - The floors of all rooms in which milk or milk products are processed, handled or stored, or in which milk containers, equipment and utensils are washed, shall be constructed of concrete or other equally impervious and easily cleanable material; and shall be smooth, properly sloped, provided with trapped drains and kept in good repair. Provided, that cold-storage rooms used for storing milk and milk products need not be provided with floor drains when the floors are sloped to drain to one or more exits. Provided further, that storage rooms for storing dry ingredients and/or packaging materials need not be provided with drains and the floors may be constructed of tightly joined wood.

2. WALLS AND CEILINGS--CONSTRUCTION - Walls and ceilings of rooms in which milk or milk products are handled, processed or stored or in which milk

containers, utensils and equipment are washed, shall have a smooth, washable, light-colored surface and be in good repair.

3. DOORS AND WINDOWS - Effective means shall be provided to prevent the access of flies and rodents. All openings to the outside shall have solid doors or glazed windows which shall be closed during dusty weather.

4. LIGHTING AND VENTILATION - All rooms in which milk or milk products are handled, processed or stored and/or in which milk containers, equipment and utensils are washed shall be well lighted and well ventilated.

5. SEPARATE ROOMS –

(a) There shall be separate rooms or areas for:

(i) The pasteurizing, processing, cooling and packaging of milk and milk products.

(ii) The cleaning of milk cans, bottles and cases.

(iii) Cleaning and sanitizing facilities for milk tank trucks in plants receiving milk in such tanks.

(iv) Receiving cans of milk and milk products in plants receiving such cans.

Rooms in which milk or milk products are handled, processed or stored, or in which milk containers, utensils and equipment are washed or stored, shall not open directly into any stable or place where animals are kept. All rooms shall be sufficient size for their intended purpose. Designated area or rooms shall be provided for the receiving, handling and storage of returned packaged milk and milk products.

6. TOILET-SEWAGE DISPOSAL FACILITIES - Every milk plant shall be provided with toilet facilities. Toilet rooms shall not open directly into any room in which milk and/or milk products are processed. Toilet rooms shall be completely enclosed and shall have tight-fitting, self-closing doors. Dressing rooms, toilet rooms and fixtures shall be kept in a clean condition, in good repair and shall be well ventilated and well lighted. Sewage and other liquid wastes shall be disposed of in a sanitary manner.

7. WATER SUPPLY - Water for milk plant purposes shall be from a supply properly located, protected and operated and shall be easily accessible, adequate and of a safe, sanitary quality.

8. HAND-WASHING FACILITIES - Convenient hand-washing facilities shall be provided, including hot and cold or warm running water; soap and individual sanitary towels or other hand-drying devices. Hand-washing facilities shall be kept in a clean condition and in good repair.

9. MILK PLANT CLEANLINESS - All rooms in which milk and milk products are handled, processed or stored and/or in which containers, utensils or equipment are washed or stored, shall be kept clean, neat and free of evidence of insects and rodents. Only equipment directly related to the processing operations or to handling of containers, utensils and equipment shall be permitted in the pasteurizing, processing, cooling, packaging and bulk milk storage rooms.

10. SANITARY PIPING - All sanitary piping, fittings and connections which are exposed to milk or milk products or from which liquids may drip, drain, or be drawn into milk or milk products shall consist of smooth, impervious, corrosion-resistant, nontoxic, easily cleanable material. All piping shall be in good repair. Pasteurized milk and milk products shall be conducted from one piece of equipment to another only through sanitary piping.

11. CONSTRUCTION AND REPAIR OF CONTAINERS AND EQUIPMENT - All multi-use containers and equipment with which milk or milk products come into contact shall be of smooth, impervious, corrosion-resistant, nontoxic material; shall be constructed for ease of cleaning; and shall be kept in good repair. All single-service containers, closures, gaskets and other articles with which milk or milk products come in contact shall be nontoxic and shall have been manufactured packaged, transported and handled in a sanitary manner. Articles intended for single- service use shall not be reused.

12. CLEANING AND SANITIZING OF CONTAINERS AND EQUIPMENT - The product-contact surfaces of all multi-use containers, utensils and equipment used in the transportation, processing, handling and storage of milk and milk products shall be effectively cleaned and shall be sanitized before each use. Provided, that piping, equipment and containers used to process, conduct or package aseptically processed milk and milk products, beyond the final heat treatment process, shall be sterilized before any aseptically processed milk or milk product is packaged and shall be resterilized whenever any unsterile product has contaminated it.

13. STORAGE OF CLEANED CONTAINERS AND EQUIPMENT - After cleaning, all multi-use milk or milk products containers, utensils and equipment shall be transported and stored to assure complete drainage and shall be protected from contamination before use.

14. STORAGE OF SINGLE-SERVICE CONTAINERS, UTENSILS AND MATERIALS - Single-service caps, cap stock, parchment paper, containers, gaskets and other single-service articles for use in contact with milk and milk products shall be purchased and stored in sanitary tubes, wrappings or cartons; shall be kept therein in a clean, dry place until used; and shall be handled in a sanitary manner.

15. PROTECTION FROM CONTAMINATION - Milk plant operations, equipment and facilities shall be located and conducted to prevent any contamination of milk or milk products, ingredients, equipment, containers and utensils. All milk or milk products or ingredients which have been spilled, overflowed or leaked shall be discarded. The processing or handling of products other than milk or milk products in the pasteurization plant shall be performed to preclude the

contamination of such milk and milk products. The storage, handling and use of poisonous or toxic materials shall be performed to preclude the contamination of milk and milk products, or ingredients of such milk and milk products or the product-contact surfaces of all equipment, containers or utensils.

16. PASTEURIZATION--ASEPTIC PROCESSING - Pasteurization shall be performed as defined in Section 1. Aseptic processing shall be performed in accordance with 21 CFR 113.

17. COOLING OF MILK - All raw milk and milk products shall be maintained at 7°C (45°F) or less until processed. All pasteurized milk and milk products, except those to be cultured, shall be cooled immediately prior to filling or packaging, in approved equipment, to a temperature of 7°C (45°F) or less. All pasteurized milk and milk products shall be stored at a temperature of 7°C(45°F) or less. On delivery vehicles, the temperature of milk and milk products shall not exceed 7°C(45°F). Every room or tank in which milk or milk products are stored shall be equipped with an accurate thermometer. Provided, that aseptically processed milk and milk products to be packaged in hermetically sealed containers shall be exempt from the cooling requirements of this item.

18. BOTTLING AND PACKAGING - Bottling and packaging of milk and milk products shall be done at the place of processing or pasteurization in approved mechanical equipment.

19. CAPPING - Capping or closing of milk and milk product containers shall be done in a sanitary manner by approved mechanical capping and/or closing equipment. The cap or closure shall be designed and applied in such a manner that the pouring lip is protected to at least its largest diameter and, with regard to fluid product containers, removal cannot be made without detection.

20. PERSONNEL--CLEANLINESS - Hands shall be thoroughly washed before commencing plant functions and as often as may be required to remove soil and contamination. No employee shall resume work after using the toilet room without thoroughly washing their hands. All persons, while engaged in the processing, pasteurization, handling, storage or transportation of milk, milk products, containers, equipment or utensils shall wear clean outer garments. All persons, while engaged in the processing of milk or milk products shall wear adequate hair coverings and shall not use tobacco.

21. VEHICLES - All vehicles used for the transportation of pasteurized milk and milk products shall be constructed and operated so that the milk and milk products are maintained at 7°C (45°F) or less, and are protected from sun, freezing and contamination.

22. SURROUNDINGS - Milk plant surroundings shall be kept neat, clean and free from conditions which might attract or harbor flies, other insects and rodents or which otherwise constitute a nuisance.

23. Requirements for HACCP systems in Dairy Plants can be found in Appendix K, 2003 Pasteurized Milk Ordinance.

C. SANITATION REQUIREMENTS FOR NOT-PASTEURIZED MILK AND MILK PRODUCTS - Guidelines for determining compliance with these requirements may be found in the Grade A Pasteurized Milk Ordinance.

A milk distributor who sells not-pasteurized milk or milk products, in the State of Maine shall comply with: Section VI, B (1), (2), (3), (4), (6), (7), (8), (9), (11), (12), (13), (14), (15), (17) (20), and (22), and

1. SEPARATE ROOMS –

(a) There shall be separate rooms or areas for:

(i) The processing, packaging and cooling of not pasteurized milk and milk products.

(ii) The cleaning of milk cans, bottles and cases.

(b) Rooms or areas in which not pasteurized milk or milk products are handled, processed or stored, or in which milk containers, utensils and equipment are washed or stored, shall not open directly into any stable or any place where animals are kept, and shall have a self closing door. All rooms shall be of sufficient size for their intended purpose.

2. MILK PLANT CLEANLINESS - All rooms in which milk and milk products are handled, processed or stored and/or in which containers, utensils or equipment are washed or stored, shall be kept clean, neat and free of evidence of insects and rodents. Only equipment directly related to the processing operations or to handling of containers, utensils and equipment shall be permitted in the processing, cooling, packaging and bulk milk storage rooms.

3. CLEANING AND SANITIZING OF CONTAINERS AND EQUIPMENT - The product-contact surfaces of all multi-use containers used in the transportation, processing and storage of not pasteurized milk and milk products shall be effectively cleaned and shall be sanitized before each use.

4. PROTECTION FROM CONTAMINATION - Milk plant operations, equipment and facilities shall be located and conducted to prevent any contamination of milk or milk products, ingredients, equipment, containers and utensils. All milk or milk products or ingredients which have been spilled, overflowed or leaked shall be discarded. The processing or handling of products other than milk or milk products in the plant shall be performed to preclude the contamination of such milk and milk products. The storage, handling and use of poisonous or toxic materials shall be performed to preclude the contamination of milk and milk products, or ingredients of such milk and milk products or the product-contact surfaces of all equipment, containers or utensils.

5. COOLING OF NOT PASTEURIZED MILK - All not pasteurized milk and milk products shall be maintained at 7°C (45°F) or less until processed or sold.

6. BOTTLING AND PACKAGING - Bottling and packaging of not pasteurized milk and milk products shall be done at the place of processing in a manner approved by the Department.

7. VEHICLES - All vehicles used in the transportation of not pasteurized milk and milk products shall be constructed and operated so that the milk and milk products are maintained at 7°C (45°F) or less, and are protected from sun, from freezing and from contamination.

D. SANITATION REQUIREMENT FOR BULK MILK HAULER/SAMPLERS AND MILK TANK TRUCKS - Guidelines for determining compliance with these requirements may be found in the Grade A Pasteurized Milk Ordinance.

1. Samples and Sampling Equipment

(a) Sample containers shall be stored to preclude contamination.

(b) Sample box shall be in good repair and kept clean.

(c) Sample transfer instrument shall be cleaned and sanitized to insure that proper samples are collected.

(d) Sample transfer instrument container is provided and adequate means for maintaining sanitizer solutions is on hand.

(e) Samples are properly stored to preclude contamination.

(f) Sample storage compartment shall be clean.

(g) Samples are maintained at an acceptable temperature (32°F to 40°F) and a temperature control sample is provided.

(h) An approved thermometer is available for use by the sampler. (Accuracy of thermometer checked each six months with check recorded on carrying case).

2. PRODUCT TEMPERATURE

(a) Product temperature must meet all the requirements of B(17) Cooling of milk.

(b) Product that remains in external transfer systems that exceeds 45°F is discarded. (This includes pumps, hoses, air elimination equipment or metering systems)

3. CONSTRUCTION AND REPAIR REQUIREMENTS

(a) The bulk milk pick-up tanker and all appurtenances shall meet applicable requirements of B(10) Sanitary piping and B(11) Construction and Repair of Containers and Equipment.

(b) The interior of the bulk milk pickup tanker shall be constructed of smooth, nonabsorbent, corrosion-resistant, nontoxic material and it shall be maintained in good repair.

(c) The appurtenances of the bulk milk pickup tanker includes hoses, pumps and fittings, and shall be constructed of smooth, non-toxic cleanable material and shall be maintained in good repair. Where flexibility is required, the fluid transfer system shall be free draining and so supported to maintain uniform slope and alignment. They shall be easily disassembled and accessible for inspection.

(d) The cabinet portion(s) of the tank, where applicable, used for storage of appurtenances and sampling equipment shall be constructed to preclude contamination by dust, dirt, and be clean and in good repair.

(e) The bulk milk pickup tanker dome lid assembly, vent and dust cover shall be designed to protect the tank and milk from contamination.

4. CLEANING AND SANITIZING REQUIREMENTS

(a) The product contact surfaces of all multi-use containers, utensils and equipment used in the transportation, processing, handling and storage of milk or milk products shall be effectively cleaned and shall be sanitized before each use.

(b) The bulk milk pickup tanker shall be cleaned and sanitized prior to its first use. When time elapsed after cleaning and sanitizing before first use exceeds 72 hours, the tank must be re-sanitized.

(c) It is allowable to pickup multiple loads continuously within a 24-hour period provided that the bulk milk pickup tanker is washed after each day of use.

5. EXTERIOR CONDITION OF TANK - The exterior of the bulk milk pickup tanker is properly constructed and in good repair. Defects and damage that would adversely affect products contained in the bulk milk pickup tanker are pointed out on the inspection sheet and corrective actions are prescribed. Cleanliness of the bulk milk pickup tanker exterior is evaluated with consideration of existing weather and environmental conditions.

6. WASH AND SANITIZE RECORD

(a) The bulk milk hauler/sampler shall be responsible for assuring that the bulk milk pickup tanker has been properly cleaned and sanitized. A bulk

milk pickup tanker without proper cleaning and sanitizing documentation shall not be loaded or unloaded until the proper cleaning and sanitization can be verified.

(b) A cleaning and sanitizing tag shall be affixed to the outlet valve of the bulk milk pickup tanker until the bulk milk pickup tanker is next washed. When the bulk milk pickup tanker is washed, the previous cleaning and sanitizing tag shall be removed and stored at the location where the bulk milk pickup tanker was washed for a period of no less than 15 days.

(c) The following information shall be recorded on the cleaning and sanitization tag:

(i) Identification of the bulk milk pickup tanker.

(ii) Date and time of day the bulk milk pickup tanker was cleaned and sanitized.

(iii) Location where the bulk milk pickup tanker was cleaned and sanitized.

(iv) Signature or initials of person who cleaned and sanitized the bulk milk pickup tanker.

(d) The maintenance of all information on the cleaning and sanitizing tag shall be the responsibility of bulk milk hauler/sampler or the milk tank truck operator.

7. LOCATION OF LAST CLEANING - The location of the last cleaning shall be verified by the Department during any bulk milk pickup tanker inspection and recorded on the inspection sheet.

8. LABELING - The maintenance of all pertinent information on all shipping documents, shipping invoices, bills of lading or weight tickets is the responsibility of the bulk milk hauler/sampler. A bulk milk pickup tanker transporting raw, heat treated or pasteurized milk and milk products to a milk plant from another milk plant, receiving or transfer station is required to be marked with the name and address of milk plant or hauler and the bulk milk pickup tanker shall be under a proper seal. All shipping documents must contain the following information:

(a) Shipper’s name, address and permit number. Each bulk milk pickup tanker load of milk shall include the IMS Bulk Tank Unit (BTU) identification number(s) or the IMS listed Plant Number (for farm groups listed with a plant) on the weight ticket or manifest.

(b) Permit identification of hauler, if not an employee of the shipper.

(c) Point of origin of shipment.

(d) Tanker identification number.

(e) Name of product.

(f) Weight of product.

(g) Temperature of product when loaded.

(h) Date of shipment.

(i) Name of supervising Regulatory Agency at the point of origin of shipment.

(j) Whether the contents are raw, pasteurized, or in the case of cream, lowfat or skim milk, whether it has been heat-treated.

(k) Seal number on inlet, outlet, wash connections and vents.

(l) Grade of product.

All information contained on the above described documents shall be verified by the Department and recorded on the appropriate inspection sheet for any bulk milk tankers under inspection.

9. VEHICLES AND TANKERS PROPERLY IDENTIFIED - It shall be the responsibility of the bulk milk pickup tanker owner or operator to insure the proper and legible identification of the bulk milk pickup tankers in their possession.

10. PREVIOUS INSPECTION SHEET AVAILABLE - When a bulk milk pickup tanker transports milk and milk products from one regulatory jurisdiction to another it is not necessary to inspect each tanker upon each arrival. Tank truck owners and operators shall carry proof of annual inspection from a recognized Regulatory Agency. A bulk milk pickup tanker may be inspected at any time or at the discretion of any Regulatory Agency responsible for the milk supply.

11. SAMPLE CHAIN OF CUSTODY - When samples for official laboratory analysis are transported by any individual where sample chain-of-custody may be established, the driver may be required to carry a valid permit for the collection of samples for official laboratory analysis. As an alternative, a sample case sealed as required by the Department may be accepted.

E. SANITATION REQUIREMENTS FOR SINGLE SERVICE CONTAINER MANUFACTURERS - Guidelines for determining compliance with these requirements may be found in the Grade A Pasteurized Milk Ordinance.

Single service container manufacturers shall comply with Section VI, B(1-9), (15), (20), (22), and

1. Locker and lunch rooms:

   (a) Separated from plant operation; self closing doors.

   (b) Eating/storage of food prohibited in fabricating and storage room.

   (c) Locker and lunchrooms clean.

   (d) Covered, impervious trash containers provided.

   (e) Handwashing facilities provided.

   (f) Employee handwashing signs posted.

2. Disposal of waste:

   (a) Refuse in plant properly stored in covered containers.

   (b) Refuse containers properly identified.

   (c) Refuse stored outside plant.

3. Storage of materials and finished products:

   (a) Elevated off the floor and away from wall.

   (b) Single service articles in process protected from contamination

   (c) Stored in clean, dry place, protected from splash, insects, and dust.

   (d) Containers and closures stored in original cartons and sealed until used; partially used cartons resealed during storage.

   (e) Containers for reuse materials are covered, clean and identified.

4. Fabricating, processing and packaging equipment:

   (a) Contact surfaces clean.

   (b) Materials in process protected from contamination; overhead shields.

   (c) Fasteners, guides, hangers, supports and baffles properly constructed; makeshift devices not used.

   (d) Container contact surfaces properly constructed; in good repair.

(e) Wax coating applied properly; wax temperature maintained.

(f) Grinders, shredders and similar equipment properly installed; protected from contamination.

(g) Resin storage facilities properly filtered; air tubes covered.

5. Equipment and materials for construction of containers and closures:

(a) Equipment thoroughly cleaned after use of non-food-grade materials.

(b) Plastic sheeting, laminated paper, metal, and paper board blanks from approved source.

(c) Sanitary lubricants used on contact surface.

(d) Proper separation of raw and non-food-grade materials.

(e) Containers or materials for containers not used if on floor.

6. Waxes, adhesives, and inks:

(a) Properly stored in covered containers.

(b) Materials not in use properly stored.

(c) Nontoxic; impart not flavor or odor.

(d) Transfer containers clean; identified.

7. Handling of containers and equipment:

(a) Handling of product contact surfaces shall be kept to a minimum.

8. Wrapping and shipping:

(a) Single service articles protected from contamination prior to use.

(b) Packaged contents protected.

(c) Transportation vehicles clean; in good repair.

(d) Paper board containers, wrappers and dividers not reused.

(e) Packaging materials in compliance.

9. Identification and records:

   (a) Plant identification on outer wrapping.

   (b) Required bacteriological tests on file.

   (c) All materials and components in compliance; records on file.

10. Surroundings:

   (a) Surroundings neat and clean and free of breeding areas

   (b) Driveways graded; no standing water.

SECTION VII - ANIMAL HEALTH

A. Tuberculosis Testing Requirements

All milk shall be from herds in areas ~~which~~ that are located in a Modified Accredited Advanced Tuberculosis status or greater as determined by the U.S. Department of Agriculture. Provided, that in an area which fails to maintain such status, any herd shall have been accredited by said Department as tuberculosis free or shall have passed an annual tuberculosis test, or the area shall have established a tuberculosis testing protocol for livestock that assures tuberculosis protection and surveillance of the dairy industry within the area and that it is approved by the Food and Drug Administration, the U.S. Department of Agriculture, and the Department. And also provided, that milk from cow, goat, sheep, water buffalo or other hooved mammal herds used for not pasteurized product production shall be from herds which have been tested every 3 years for tuberculosis with an allowable maximum grace period not exceeding 2 months.

B. Brucellosis Testing Requirements

1. All cow milk shall be from herds under a brucellosis eradication program ~~which~~ that meets one of the following conditions:

~~A.~~ (a) Located in a Certified Brucellosis-Free Area as defined by the U.S. Department of Agriculture and enrolled in the testing program for such areas; or

~~B.~~ (b) Meet U.S. Department of Agriculture requirements for an individually certified brucellosis-free herd; or

~~C.~~ (c) Participate in a milk ring testing program at least two times per year at approximately 180 day intervals and all herds with positive milk ring test results

shall have the entire herd blood tested within 30 days from the date of the laboratory ring test; or

~~D.~~ (d) Have an individual blood agglutination test annually with an allowable maximum grace period not exceeding 2 months.

~~For diseases other than brucellosis and tuberculosis, the Department shall require such physical, chemical or bacteriological tests as it deems necessary. The diagnosis of other diseases in dairy cattle shall be based upon the findings of a licensed veterinarian or a veterinarian in the employ of an official agency. Any diseased animal disclosed by such test(s) shall be disposed of as the Department directs.~~

2. Goat, ~~milk and~~ sheep, water buffalo, or any other hooved mammal except cow milk for milk product production ~~pasteurization, or ultra-pasteurization or aseptic processing~~ shall be from a herd or flock, ~~which~~ that meets one of the following conditions:

(a) ~~which~~ Has passed an annual whole herd or flock ~~tuberculosis and~~ brucellosis test as recommended by the State Veterinarian or USDA Area Veterinarian in Charge (AVIC); or

(b) ~~From a herd or flock which~~ Has passed an initial whole herd brucellosis test, followed ~~only~~ by testing any outside, new acquisition replacement animals ~~or any animals entering the milking group or sold as dairy animals~~; or ~~by~~

(c) Has passed a USDA approved bulk milk test, at USDA recommended frequency, with an implementation date based on availability of the test; or

(d) Has passed an annual random blood-testing program sufficient to provide a confidence level of 99% with a P value of 0.05. Any herd or flock with one (1) or more confirmed positive animals shall go to 100% testing until the whole herd tests show no positive animals are found.

The following table will provide the random sampling size needed to achieve 99% confidence with a P value of 0.05.

Herd/Flock Size	**Sampling Size**	**Herd/Flock Size**	**Sampling Size**
20	20	500	82
50	41	600	83
100	59	700	84
150	67	800	85
200	72	1000	86

250	75	1400	87
300	77	1800	88
350	79	4000	89
400	80	10000	89
450	81	100000	90

~~Milk from goat herds used for raw milk product production shall be from herds which have been tested every 3 years for tuberculosis with an allowable maximum grace period not exceeding 2 months.~~

C. Other Testing Requirements

For diseases other than brucellosis and tuberculosis, the Department shall require such physical, chemical or bacteriological tests as it deems necessary. The diagnosis of other diseases in dairy cattle shall be based upon the findings of a licensed veterinarian or a veterinarian in the employ of an official agency.

SECTION VIII - TRANSFERRING; DELIVERY CONTAINERS; COOLING

Except as permitted in this section, no milk producer, milk hauler or distributor shall transfer milk or milk products from one container or milk tank truck to another on the street, in any vehicle, store or in any place except a milk plant, receiving station, transfer station or milkhouse especially used for that purpose. The dipping or ladling of milk or fluid milk products is prohibited.

It shall be unlawful to sell or serve any milk or fluid milk product except in the individual, original container received from the distributor, or from an approved bulk dispenser. Provided, that this requirement shall not apply to milk for mixed drinks requiring less than 236 milliliters (½ pint) of milk, or to cream, whipped cream or half-and-half which is consumed on the premises and which may be served from the original container of not more than 1.9 liter (½ gallon) capacity or from a bulk dispenser approved for such service by the Department.

It shall be unlawful to sell or serve any milk or milk product which has not been maintained at the temperature set forth in Section V of this rule. If containers of pasteurized or not pasteurized milk or milk products are stored in ice, the storage container shall be properly drained.

SECTION IX - MILK AND MILK PRODUCTS FROM POINTS BEYOND THE LIMITS OF ROUTINE INSPECTION

Milk and milk products from points beyond the limits of routine inspection of the State of Maine, may be sold in Maine, provided they are produced and pasteurized, ultra-pasteurized or aseptically processed under regulations which are substantially equivalent to this rule and have been awarded an acceptable milk sanitation compliance and enforcement rating, made by a State Milk Sanitation Rating Officer certified by the Food and Drug Administration.

SECTION X - PERSONNEL HEALTH

Persons infected with any disease capable of being transmitted to others through the contamination of food shall not work at a milk plant in any capacity which brings them into direct contact with finished products or which brings them into direct contact with associated processed milk product contact surfaces.

SECTION XI - PROCEDURE WHEN INFECTION OR HIGH RISK OF INFECTION IS DISCOVERED

When a person who may have handled pasteurized, aseptically processed or not pasteurized milk or milk products or pasteurized, aseptically processed, or not pasteurized milk product contact surfaces meets one or more of the conditions specified below in Section XI, the Department is authorized to require any of all of the following measures:

A. Milk plant operators who have received reports, under this section, from employees who have handled pasteurized milk, pasteurized milk products or associated product contact surfaces shall immediately report these facts to the ~~appropriate milk Regulatory Agency~~Department.

Dairy plant employees (or applicants to become employees) shall be instructed by the dairy plant that the employee or applicant is responsible to report to the dairy plant management, in a manner that allows the dairy plant to prevent the likelihood of disease transmission of diseases that are transmissible through food, if the employee or applicant:

1. Is diagnosed with an illness due to Hepatitis A virus, Salmonella Typhi, Shigella Species, Norwalk and Norwalk-like Viruses, Staphylococcus aureus, Streptococcus Pyogenes, Escheriachia coli 0157:H7, enterohemorrhagic Escherichia coli, enterotoxigenic Escherichia coli, Campylobacter jejuni, Entamoeba histolytica, Giardia lamblia, Non-typhoidal Salmonella, Rotovirus, Taenia Solium, Yersinia enterocolitica, Vibrio cholerae 01 or other infectious disease that has been declared by the Secretary of Health and Human Services to be transmissible to others through the handling of food, or has been clearly shown to be so based upon verifiable epidemiological data; or

2. Is exposed to, or suspected of causing, a confirmed foodborne disease outbreak of one of the diseases specified in A above, including an outbreak at an event such as a family meal, church supper or ethnic festival because the applicant or employee:

(a) Prepared food implicated in the outbreak, or

(b) Consumed food implicated in the outbreak, or

(c) Consumed food at the event prepared by a person who is infected or ill.

3. Lives in the same household as a person who attends or works in a day care center or school, similar institution experiencing a confirmed outbreak of one of the diseases specified in A above.

Similarly, dairy plant employees shall be instructed by the dairy plant management to report to the dairy plant management if the employee (or applicant):

4. Has a symptom associated with acute gastrointestinal illness such as: abdominal cramps or discomfort, diarrhea, fever, loss of appetite for three or more days, vomiting, jaundice, or

5. Has a pustular lesion such as a boil or infection wound that is:

(a) On the hands, wrists or exposed portions of the arms, unless the lesion is covered by a durable, moisture proof, tight-fitting barrier, or

(b) On other parts of the body if the lesion is open or draining, unless the lesion is covered by a durable, moisture proof, tight-fitting barrier.

B. The immediate restricting of that person from duties which require handling finished product, such as pasteurized or not pasteurized milk or milk products or the handling of related product contact surfaces. This restriction may be lifted after an appropriate medical clearance or cessation of symptoms or both, according to the following criteria:

REMOVAL OF RESTRICTIONS WHEN INFECTION OR HIGH RISK OF INFECTION IS DISCOVERED

Health Status	Removing Restrictions
a. Is diagnosed with an illness due to Hepatitis A virus, Salmonella typhi, Shigella species, Norwalk and Norwalk-like Viruses, Staphylococcus aureus, Streptococcus pyogenes, Escherichia coli 0157:H7, enterohemorrhagic Escherichia coli, enterotoxigenic, Escherichia coli, Campylobactor jejuni, Entamoeba histolytica, Giardia lamblia, Non-typhoidal Salmonella, Rotovirus, Taenia solium, Arsine enterocolitica, Vibrio cholerae 01 or other infectious or communicable disease that has been declared by the Secretary of Health and Human Services to be transmissible to others through the handling of food or has been clearly shown to be so based upon verifiable epidemiological data.	Restrictions lifted by Medical clearance.
b. Meeting a high risk scenario as specified	Restrictions lifted when symptoms

in Section X ((b) or (c)) and/or experiencing symptoms in Section XI (4, 5 or 6).	cease or medical documentation is provided that infection does not exist.
c. Asymptomatic, but stools positive for Salmonella typhi, Shigella or Escherichia coli 0157:H7	Restrictions lifted by medical clearance.
d. Past illness from Salmonella typhi, Shigella, Escherichia coli 0157:H7 or other human pathogens for which humans have been determined to be carriers.	Restrictions lifted by medical clearance.
e. In the case of diagnosed or suspected Hepatitis A, onset of jaundice within the last seven (7) days.	Restrictions lifted by medical clearance.
f. In the case of diagnosed or suspected Hepatitis A, onset of jaundice occurred more than seven (7) days ago.	Restrictions lifted by medical clearance or jaundice ceases.

B. The immediate exclusion of the affected dairy products from distribution and use when medically appropriate (i.e., a medical evaluation of the sequence of events indicates that contamination of product may have occurred).

C. The immediate requesting of medical and bacteriological examination of the person at risk. (Note: Persons at risk who decline to be examined may be reassigned to duties where they will not be required to handle finished products, such as pasteurized or aseptically processed or not pasteurized milk or milk products, and associated product contact surfaces).

SECTION XII – EXAMINATION OF MILK AND MILK PRODUCTS

A. SAMPLE COLLECTION

1. It shall be the responsibility of the milk hauler to collect a representative sample of milk from each farm bulk tank prior to transferring milk from a farm bulk tank, truck or other container. All samples shall be collected and delivered to a milk plant, receiving station, transfer station or other location approved by the Department. During any consecutive six months, at least four samples of raw milk for pasteurization shall be collected, in at least four separate months, except when three months show a month containing two sampling dates separated by at least 20 days, and delivered in accordance with this Section from each producer. These samples shall be obtained under the direction of the Department or shall be taken from each producer under the direction of the Department.

2. During any consecutive six months, at least four samples of raw milk for pasteurization, ultra-pasteurization or aseptic processing, collected in at least four separate months, except when three months show a month containing two sampling dates separated by at least 20 days, shall be taken by the Department,

from each milk plant after receipt of the milk by the plant and prior to pasteurization, ultra-pasteurization or aseptic processing.

3. During any consecutive six months, at least four samples of heat treated milk products, from plants offering such products for sale, shall be collected in at least four separate months, except when three months show a month containing two sampling dates separated by at least 20 days, by the Department.

4. During any consecutive six months, at least four samples of pasteurized and aseptically processed milk, flavored milk, flavored low-fat milk, flavored skim milk, each fat level of low-fat milk and each milk product defined in this rule, shall be collected in at least four separate months, except when three months show a month containing two sampling dates separated by at least 20 days, from every milk plant, by the Department.

5. During any consecutive six months, at least four samples of milk and milk products not pasteurized shall be collected in at least four separate months, except when three months show a month containing two sampling dates separated by at least 20 days, from every milk distributor, by the Department.

6. During any consecutive 6 months at least 4 sample~~s~~ sets of single service containers from each manufacturing line, shall be collected by the Department, in at least 4 separate months, except when 3 months show a month containing 2 sampling dates separated by at least 20 days from every manufacturer. A sample set is at least four (4) containers.

7. Once every 3 months at least 4 samples of multi-use containers, shall be collected by the Department from each milk distributor.

8. Samples of milk and milk products shall be taken while in the possession of the producer or distributor at any time prior to delivery to the store or consumer. Samples of milk and milk products from dairy retail stores, food service establishments, grocery stores and other places where milk and milk products are sold shall be examined periodically as determined by the Department and the results of such examination shall be used to determine compliance with Sections II and VIII. Proprietors of such establishments shall furnish the Department, upon request, with the names of all distributors from whom milk or milk products are obtained.

9. Milk and milk products not produced continuously throughout the year are exempt from being sampled 4 times in any 6 consecutive months. Frozen dairy desserts and eggnog shall be sampled 1 time, each month during the production season.

10. Water samples, from the water supply for the milk house and milking operations, shall be taken every 3 years. Water supplies with buried well casing seals, shall be sampled at intervals no greater than 6 months apart. Water samples, from the water supply for milk plant purposes, shall be sampled every 6 months for Interstate Milk Shippers plants and every 12 months for all other plants. Recirculating water shall be sampled every 6 months for all dairy plants. Dairy

farms and dairy plants who use municipal water supplies shall be exempt from these water testing requirements.

B. EXAMINATION OF SAMPLES

1. Required bacterial counts, somatic cell counts and cooling temperature checks shall be performed on raw milk from the farm bulk tank. In addition, drug tests of each producer's milk shall be conducted at least four times during any consecutive 6 months.

2. Required bacterial counts, somatic cell counts and cooling temperature checks shall be performed on raw milk for pasteurization.

3. Required bacterial counts, coliform determinations, somatic cell counts and cooling temperature checks shall be performed on heat treated milk products.

4. Required bacterial counts, drug tests, coliform determinations, phosphatase and cooling temperature checks shall be performed on pasteurized milk and milk products. Required drug residue tests shall be performed on aseptically processed milk and milk products.

5. Required bacterial counts, drug tests, coliform determinations, and cooling temperature checks shall be performed on milk and milk products not pasteurized.

6. Required bacterial counts shall be performed on single service and multi-use containers.

7. When multiple samples of the same milk or milk products, except for aseptically processed milk and milk products, are collected from the same producer or processor from multiple tanks or silos on the same day, the laboratory results are averaged arithmetically by the Department and recorded as the official results for that day. This is applicable for bacterial (standard plate count and coliform), somatic cell count and temperature determinations only.

8. Milk from animals not currently in this Rule may be labeled as Grade "A" and IMS listed upon FDA's acceptance of validated drug residue test methods for compliance with this Section and Section XIII.

C. VIOLATIONS

1. Whenever two of the last four bacterial counts (except those for aseptically processed milk and milk products), somatic cell count, coliform determinations, or cooling temperatures, taken on separate days, exceed the limit of the standard for the milk and/or milk products, the Department shall send a written notice to the producer or milk distributor. This notice shall be in effect so long as two of the last four samples exceed the limit of the standard. An additional sample shall be taken within 21 days of the sending of such notice, but not before the lapse of 3 days.

2. When a milk plant's product is in violation of standard for 3 of the last 5 tests, the plant's senior management will be notified (by telephone and certified letter) to suspend distribution of product. The Department will also be notified (by telephone and/or pager) and they will conduct a plant inspection as soon as possible. This inspection shall note the ~~probably~~ probable cause of the violation(s) and any corrective action(s) necessary. After inspection, the plant will be allowed to resume distribution of product. Product will be sampled on an accelerated schedule (not more than 2 samples per week for 3 weeks). Once the plant has been inspected and allowed to resume distribution, previous test history will not be used to calculate 2 out of 4 or 3 out of 5 violations. Calculation will be based on test results from the accelerated sampling schedule.

3. When a producer's bulk tank milk is in violation of standard for 3 of the last 5 samples, the permit shall be suspended by the department and the following steps shall be taken: ~~(a) department shall suspend the producer's permit, and issue a temporary permit,~~ ~~(b)~~ (a) For violation of bacterial standard, the Department shall conduct a farm inspection. This inspection shall note the probable cause of the violation(s) and any corrective action(s) necessary. ~~The producer's permit shall be restored upon inspection~~. A permit shall be issued upon inspection. (b) For violation of somatic cell standard, permit will be issued when an official bulk tank sample is tested within the standard established by this Rule at an official laboratory.

   For bacterial or somatic cell violations, the producer's bulk tank milk will be sampled on an accelerated schedule (not more than 2 samples per week for 3 weeks). Once the accelerated sampling has begun, the previous test history will not be used to calculate 2 out of 4 or 3 out of 5 violations. Calculations will be based on test results from the accelerated sampling schedule.

4. Whenever a phosphatase test is positive, the cause shall be determined. Where the cause is improper pasteurization, it shall be corrected and any milk or milk product involved shall not be offered for sale.

5. Whenever a pesticide residue test is positive, an investigation shall be made to determine the cause and the cause shall be corrected. An additional sample shall be taken and tested for pesticide residues and no milk or milk products shall be offered for sale until it is shown by a subsequent sample to be free of pesticide residues or below the actionable levels established for such residues.

6. Whenever a drug residue test is confirmed positive, an investigation shall be made to determine the cause, and the cause shall be corrected in accordance with the provisions of Section XIII.

7. Whenever a container or containers of aseptically processed milk or milk product is found to be unsterile, due to under-processing, the Department shall consider this to be an imminent hazard to public health and shall suspend the permit of the milk plant for the sale of aseptically processed milk and milk products. No aseptically processed milk and milk product shall be sold until it can be shown that the processes, equipment and procedures used are suitable for

consistent production of a sterile product. All product from the lot that was found to contain one or more unsterile units shall be recalled and disposed of as directed by the Department.

8. When single service or multi-use containers exceed the standard in 3 out of 4 samples taken at random on a given day, the Department all conduct an inspection to determine the probable cause(s) and note corrective action(s).

D. INDEPENDENT TESTING OF NOT PASTEURIZED MILK PRODUCTS

When the official milk laboratory operated by the department has tested not pasteurized milk products and determined that those milk products do not meet the standards for not pasteurized milk products established by this rule, the person operating the milk plant that processed the milk products may request further testing by an independent FDA certified laboratory. The not pasteurized milk products must not be sold pending the completion of the independent testing. Within three (3) business days of receipt by the department of a request for independent testing, the State Dairy Inspector shall obtain duplicate samples of the not pasteurized milk products from the processor. These samples will be delivered by the State Dairy Inspector to the state milk laboratory and shipped by the Department to an independent FDA certified laboratory for testing. The processor shall be responsible for the cost of shipping and testing performed by the independent FDA certified laboratory. The test results will be sent by the Department to the processor within 24-hours of receiving the results.

The not pasteurized products in dispute may be offered for sale only after testing at the official milk laboratory and the independent official laboratory has been completed and the department has received results from either laboratory which are within the established standards set forth in this rule. If the results from both the independent official laboratory and the official milk laboratory do not meet the standards for not pasteurized products, the products must not be sold until they meet the established standards.

E. METHODS OF ANALYSIS

1. Samples shall be analyzed at an official or appropriate officially designated laboratory. All sampling procedures and required laboratory examination shall be in substantial compliance with the 17 ~~16~~ th Edition of Standard Methods for the Examination of Dairy Products of the American Public Health Association, the16th Edition of Official Methods of Analysis of the Association of Official Analytical Chemists and M-a-85 FDA. Such procedures, including the certification of sample collectors, and examinations shall be evaluated in accordance with the Evaluation of Milk Laboratories, United States Public Health Service/Food and Drug Administration. Aseptically processed milk and milk products packaged in hermetically sealed containers shall be tested in accordance with the FDA's Bacteriological Analytical Manual. Examination and tests to detect adulterants, including pesticides, shall be conducted as the Department requires. Assays of milk and milk products to which vitamin(s) A

and/or D have been added, shall be made at least annually in a laboratory which is acceptable to the Department, using the test methods acceptable to FDA and other official methodology which gives statistically equivalent results to the FDA methods.

In addition, all facilities fortifying products with vitamin(s) must keep volume control records. These volume control records must cross reference the form and amount of vitamin D, vitamin A and/or vitamin A & D used with the amount of products produced and indicate a percent of expected use, plus or minus.

2. The following referenced methods of analysis are from “Official Methods of Analysis of the Association of Official Analytical Chemists", 16th Ed. (1997), which is incorporated by reference.

(a) Milkfat content--As determined by the method, "Roese-Gottlieb Method (Reference Method) (11)--Official Final Action", under the heading "Fat".

(b) Milk solids not fat content-Calculated by subtracting the milkfat content from the total solids content as determined by the method, "Method I--Official Final Action", under the heading "Total Solids".

(c) Titratable acidity--As determined by the method, "Acidity (2)--Official Final Action", or by an equivalent potentiometric method.

(d) Vitamin D content – “Vitamin D – Official Final Action”.

SECTION XIII – DRUG RESIDUE MONITORING AND FARM SURVEILLANCE

This Section is established to reference safe levels and/or establish tolerances and to assure that milk supplies are in compliance with these safe levels or established tolerances for drug residues in milk. Guidelines for determining compliance with these requirements may be found in the Grade A Pasteurized Milk Ordinance.

A. INDUSTRY RESPONSIBILITIES

1. MONITORING AND SURVEILLANCE - Milk plants shall screen all bulk milk pickup tankers, regardless of final use, for beta lactam drug residues. Specific requirements for establishing a drug residue testing program can be found in Appendix N of the 2003 Pasteurized Milk Ordinance. Additionally, other drug residues shall be screened for by employing a random sampling program on bulk milk pickup tankers. The random bulk milk pickup tanker sampling program shall represent and include, during any consecutive six months, at least four (4) samples collected in at least four (4) separate months, except when three months show a month containing two sampling dates separated by at least 20 days. Samples collected under this random sampling program shall be analyzed as specified by FDA. (Refer to M-a-75)

The bulk milk pickup tanker shall be sampled after the last producer has been picked up and before any additional commingling. The sample must be representative. Bulk milk pickup tanker testing shall be completed prior to processing the milk. Industry samplers shall be evaluated according to the requirements specified in SectionXII, THE EXAMINATION OF MILK AND MILK PRODUCTS of this rule.
Bulk milk pickup tanker samples found to be confirmed positive for drug residues shall be retained as determined necessary by the Department. ~~Milk plants shall also record all sample results and retain such records for a period of six months.~~

2. REPORTING AND FARM TRACEBACK~~.~~ – When a bulk milk pickup tanker is found to be positive for drug residues, the Department shall be immediately notified of the results and the ultimate disposition of the raw milk.

The producer samples from the bulk milk pickup tanker, found to be positive for drug residues, shall be individually tested to determine the farm of origin. The samples shall be tested as directed by the Department.

The producer shall be notified by telephone and in writing by the milk plant.

Further pickups of the violative individual producer shall be immediately discontinued, until such time, that subsequent tests are no longer positive for drug residues.

3. Record Requirements
Results of all testing may be recorded in any format acceptable to the Department and shall include at least the following information:
1. Identity of the person doing the test;
2. Identity of the bulk milk pickup tanker being tested (include the BTU number(s) of the farms present on the tanker);
3. Date/time the test was performed (Time, Day, Month and Year);
4. Identity of the test performed/lot #/any and all controls (+/-);
5. Results of the test;
6. Follow-up testing if initial test was positive/any and all controls (+/-);
7. Site where test was performed and
8. Prior test documentation shall be provided for a presumptive positive load.
Records of all sample results shall be maintained for a minimum of six (6) months by the milk plant at the location where the tests were run, and/or another location as directed by the Department.

B. DEPARTMENT RESPONSIBILITIES

1. MONITORING AND SURVEILLANCE – The Department shall monitor milk plant surveillance activities during either ~~by making~~ routine or unannounced, on-site quarterly inspections to collect samples from bulk milk pickup tankers and to review industry records of the random sampling program. Samples should be collected and analyzed from at least 10% of the bulk milk pickup tankers

scheduled to arrive on the day of the inspection. The method used shall be appropriate for the drug being analyzed and shall be capable of detecting the same drugs at the same concentrations as the method being used by industry. Receiving locations that choose to certify all receiving analysts, certified under the provisions of the NCIMS Laboratory Certification Program, are exempt from the sample collection requirements of this section. A review shall include, but not be limited to, the following:

(a) Is the program an appropriate routine monitoring program for the detection of drug residues? Is the program utilizing appropriate test methods?

(b) Is each producer's milk represented in a testing program for drug residues and tested at the frequency prescribed in A.1. above for drug residues?

(c) Is the program assuring timely notification to the Department of positive results, the ultimate disposition of the bulk milk pickup tanker milk and of the trace back to the farm of origin? Is farm pickup suspended until subsequent testing establishes the milk is no longer positive for drug residues? To satisfy these requirements:
1. There should be an agreement between the Department and industry that would specify how this notification is to take place. This notification must be "timely" for example by telephone or fax, and supported in writing
2. The ultimate disposition should either be prearranged in an agreement between the Department and the industry, or physically supervised by the Department. The milk should be disposed of in accordance with the provisions of M-I-90-9 or an FDA and Department reviewed and accepted Beta lactam milk diversion protocol for use as animal feed
3. All screening test positive (confirmed) loads must be broken down (producer traceback) using the same or an equivalent test method (M-I-96-10, latest version). Confirmation tests (load and producer trace back/permit action) shall be performed by an Official or Officially Designated Laboratory or Certified Industry Supervisor. Positive producers shall be handled in accordance with Section XIII of this rule
4. The suspension and discontinuance of farm bulk milk tank pick up is the responsibility of the industry, under the direction and supervision of the Department. At the discretion of the Department, records shall be maintained by industry and/or the Department that:
    a. Establish the identity of the producer and the identity of the load that tested positive; and
    b. Establish that no milk is picked up from the positive testing producer until the Department has fulfilled their obligations under Section XIII. B.2. of this rule and cleared the milk.

Sufficient records shall be reviewed to assure that all farm bulk milk pickup tankers are sampled before commingling and the results were made available to the appropriate BTU (s).

The Department shall also perform routine sampling and testing for drug residues determined to be necessary as outlined in Section XII and M-a-75.

2. ENFORCEMENT.

If testing reveals milk positive for drug residues, the milk shall be disposed of in a manner that removes it from the human or animal food chain.

Suspension: Any time milk is found to test positive for a drug residue, the Department shall immediately suspend the producer's Grade "A" permit or equally effective measures shall be taken to prevent the sale of milk containing drug residues.

Penalties: Future pick-ups are prohibited until subsequent testing reveals the milk is free of drug residue. The penalty shall be for the value of all milk on the contaminated load plus any costs associated with the disposition of the contaminated load. The Department may accept certification from the violative producer's milk marketing cooperative or purchaser of milk as satisfying the penalty requirements.

Reinstatement: The Grade "A" producer permit may be reinstated, or other action taken, to allow sale of milk for human food, when a representative sample taken from the producer's milk, prior to commingling with any other milk, is no longer positive for drug residue.

Follow Up: Whenever a drug residue test is positive an investigation shall be made to determine the cause.

Farm inspection is completed by the Department to determine the cause of the residue and actions taken to prevent future violations including:

(a) On farm changes in procedures necessary to prevent future occurrences as recommended by the ~~state regulatory agency~~ Department.

(b) Discussion and education on the Drug Residue Avoidance Control measures outlined in the Milk and Dairy Beef Residue Prevention Protocol.

~~Second offense: Discussion and education on the Drug Residue Avoidance Control measures outlined in the Milk and Dairy Beef Residue Prevention Protocol.~~

~~Third offense within one year: Hearing scheduled and procedures initiated by Department for revocation of Permit.~~
Permit Revocation: After a third violation in a twelve (12) month period, the Department shall initiate proceedings to revoke the producer's Grade A permit.

3. DEPARTMENT RECORDS
In the event the industry reports a positive tanker result, the Department's records should indicate the following:

a. What were the Department's directions?
b. When was the Department notified? By whom?
c. What was the identity of the load?
d. What screening and/or confirmatory test(s) were used and who were the analyst(s)?
e. What was the disposition of the adulterated milk?
f. Which producer(s) was responsible?
g. Record of negative test results prior to subsequent milk pickup from the violative producers(s).

C. ~~3~~. APPEALS PROCESS.

If a producer wishes to dispute producer traceback test results, milk from the original sample will be sent by the milk plant to the DQCI laboratory in Minnesota for high pressure liquid chromatograph (HPLC) analysis. Costs of testing will be paid by the producer if the sample is determined to be positive or false violative. Testing costs plus costs of the discarded milk will be paid by the processor if the HPLC results indicate a false positive on original screening test.

SECTION XIV - LABELING

All bottles, containers and packages enclosing milk or milk products defined in Section 1 of this rule shall be labeled in accordance with the applicable requirements of the Federal Food, Drug and Cosmetic Act as amended, the Nutrition Labeling and Education Act of 1990, and in addition, shall comply with applicable requirements of this section as follows:

A. All bottles, containers and packages enclosing milk or milk products, except milk tank trucks, storage tanks and cans of raw milk from individual dairy farms, shall be conspicuously marked with:

1. The words "Grade "A", as applicable.

2. The identity of the plant where packaged, pasteurized, ultra-pasteurized or aseptically processed.

3. The word "reconstituted" or "recombined" if the product is made by reconstitution or recombination.

4. The volume or proportion of water to be added for reconstituting or recombining in the case of concentrated milk or milk products.

5. The words "keep refrigerated after opening" in the case of aseptically processed milk and milk products.

6. In the case of aseptically processed and packaged milk or milk products, the term “UHT”.

7. The words “ultra-pasteurized” if the milk or milk product has been ultra-pasteurized.

8. The common name of the hooved mammal producing the milk ~~word "Goat" or "Sheep"~~ shall precede the name of the milk or milk product when the product is or is made from ~~goat or sheep~~ other than cattle’s milk ~~respectively~~. As an example, “Goat”, “Sheep”, or “Water Buffalo milk or milk products respectively.

9. A list of ingredients in descending order of predominance.

10. The words “not pasteurized” if the milk or milk product has not been pasteurized. ~~All farm cheese products shall be labeled in accordance with 7 M.R.S.A. § 2109.~~ This does not apply to cheese that has been aged at a temperature above 35°F for at least 60 days prior to sale.

11. The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. The name of the food shall be accompanied by a declaration indicating the presence of any characterizing flavoring, and may be accompanied by a declaration such as a traditional name of the food or the generic name of the organisms used, thereby indicating the presence of the characterizing microbial organisms or ingredients when used.

12. The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name:

    (a) The phrase "vitamin A" or "vitamin A added" or "vitamin D" or "vitamin vitamins A and D added", as appropriate. The word "vitamin" may be abbreviated "vit".

    (b) The word ”sweetened” if nutritive carbohydrate sweetener is added without the addition of characterizing flavoring.

13. The term "homogenized" may appear on the label if the dairy ingredients used are homogenized.

14. The term "pasteurized" may appear on the label if the dairy ingredients used are pasteurized.

15. The net weight or volume.

16. The word “aged” when the product has been aged for more than 60 days.

17. The lot number. The lot number shall correspond with accurate records which show time, temperature and date of production. Records will be kept for at least twelve months from the date produced.

18. The use of the term “organic”~~, or “organically grown”, or “biologically grown”~~ shall comply with ~~7 M.R.S.A. Chapter 103, Marketing Natural Organic Foods~~ The Organic Foods Production Act of 1990 and 7 CFR Part 205, National Organic Program (www.ams.usda.gov/nop/NOP/standard.html)(2005).

B. LABELING - EMERGENCY SUPPLIES

When the sale of ungraded milk or milk products is authorized during emergencies, under the terms of Section II, the label must bear the designation “ungraded.” When such labeling is not available, the Department shall take immediate steps to inform the public that the particular supply is ungraded and that the supply will be properly labeled as soon as the distributor can obtain the required labels.

C. IDENTITY LABELING - "Identity", as used in this Section, is defined as the name and address of the milk distributor at which the packaging, pasteurization, ultra-pasteurization or aseptic processing takes place.

In cases where several plants are operated by one firm, the common firm name may be utilized on milk bottles or containers, provided, that the location of the plant at which the contents were pasteurized, ultra-pasteurized or aseptically processed is also shown, either directly or by a code.

The identity labeling requirement may be interpreted as permitting plants and persons to purchase and distribute, under their own label, milk and milk products processed and packaged at another plant, provided, that the label reads, "Processed at ... (name and address)", or that the processing and packaging plant is identified by a proper code.

D. MISLEADING LABELS --The Department shall not permit the use of any misleading marks, words or endorsements upon the label. They may permit the use of registered trade designs or similar terms on the bottle cap or label when, in their opinion, they are not misleading and are not so used as to obscure the labeling required by the rule. The use of super grade designations shall not be permitted. Grade designations such as "Grade AA Pasteurized", "Selected Grade A Pasteurized", "Special Grade A Pasteurized", etc., give the consumer the impression that such a grade is significantly safer than Grade “A” milk produced under this rule. Such an implication is false, because the rule requirements for Grade “A” pasteurized, ultra-pasteurized or aseptically processed milk when properly enforced, will ensure that this grade of milk will be as safe as milk can practicably be made. Descriptive labeling terms must not be used in conjunction with the Grade “A” designation or name of the milk or milk product and must not be false or misleading.

SECTION XV- REFERENCES

1. Grade “A” Pasteurized Milk Ordinance and Appendices, ~~2001~~ 2003 Edition.

2. Grade "A" Condensed and Dry Milk Products and Condensed and Dry Whey—Supplement I to the Grade A Pasteurized Milk Ordinance, 1995 Recommendations.

3. Bacteriological Analytical Manual, 8th Edition, 1995, AOAC International, 481 North Frederick Avenue, Suite 500, Gaithersburg, MD, 20877.

4. Code of Federal Regulations, Title 21, April 1999, U.S. Government printing office, Washington, D.C.

5. Federal Food, Drug and Cosmetic Act, as Amended, 1993, U.S. Government Printing Office, Washington, D.C.

6. Nutrition Labeling and Education Act, 1990, U.S. Government Printing Office, Washington, D.C.

7. Standard Methods for the Examination of Dairy Products, ~~16~~ 17th Edition, 1992, American Public Health Association, 1015 Fifteenth Street, Washington, D.C., 20005.

8. Official Methods of Analysis, 16 th Edition, 1997, AOAC International, 481 North Frederick Avenue, Suite 500, Gaithersburg, MD, 20877.

9. Standard Methods for the Examination of Water and Wastewater, 20th Edition, 1998, American Public Health Association, 1015 Fifteenth Street, Washington, D.C., 20005.

10. 3-A Accepted Practices for the Design, Fabrication and Installation of Milk Handling Equipment, Number 606-03, March 20, 1990, International Association of Milk, Food and Environmental Sanitarians, United States Public Health Service, The Dairy Industry Committee.

11. Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments, ~~1999~~ 2005 Revision.

12. Evaluation of Milk Laboratories, ~~1995~~ 2003 Edition, Food and Drug Administration, CFSAN, Office of Field Programs, Division of HACCP, Laboratory Quality Assurance Branch, HFH-450, 6502 South Archer Road, Summit-Argo, IL 60501.

13. FDA-2400 series evaluation forms, United States Public Health Service, Food and Drug Administration, Summit-Argo, IL 60501.

14. M-a-85, Beta-Lactam Test Methods for Use Under Appendix N of the PMO, Revision ~~#7, May 21, 1999~~ #11 3-10-2004

15. M-a-75, Sampling Farm Animal Drug Residue, April 2, 1990.

16. Standard for the Fabrication of Single Service Containers and Closures for Milk and Milk Products, 1995 Revision, U.S. Department of Health Services, Public Health Service, Food and Drug Administration.

17. Methods of Making Sanitation Ratings of Milk Shippers, ~~1999~~ 2003 Edition, Public Health Service, Food and Drug Administration.

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